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FEDERAL TRADE COMMISSION

In the Matter of:	)
SCHERING-PLOUGH CORPORATION,	)
a corporation,	)
and	)
UPSHER-SMITH LABORATORIES,	) File No. D09297
a corporation,	)
and	)
AMERICAN HOME PRODUCTS,	)
a corporation.	)
----------	)

Thursday, February 14, 2002

9:30 a.m.

TRIAL VOLUME 16

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

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P R O C E E D I N G S

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JUDGE CHAPPELL: Good morning, everyone.

ALL COUNSEL: Good morning, Your Honor.

JUDGE CHAPPELL: Let's reconvene docket 9297.

Are you ready to call your next witness?

MR. NIELDS: Yes, Your Honor, but I also realized at the end of the entire day yesterday, I wasn't as fully informative as I might have been. We are going to call first today Dr. Zola Horovitz. He is a licensing and valuation expert who will be responding to Dr. Levy, and Mr. Jason Raofield, Your Honor, from my office will be handling his questioning. I think you've met him before.

JUDGE CHAPPELL: Okay, right.

MR. NIELDS: We are -- and Mr. Horovitz is only available -- is not available tomorrow, so we wanted to start him at the beginning of the day.

Upsher has a witness who I think they are very hopeful they can get on and off at the end of the day -- that, of course, will depend on how long Dr. Horovitz's testimony will go -- and that's Mr. Cannella.

MR. CURRAN: That's right, Your Honor. Mr. Cannella is here from out of town. We expect his

direct examination to be about half an hour, so we have to see how things play out, but I'm hopeful that Dr. Horovitz will be over by 4:00 or so and then Mr. Cannella will be able to provide his direct and cross testimony before the end of the day.

JUDGE CHAPPELL: And you've consulted with the opposition?

MR. CURRAN: Well, I've consulted with Mr. Nields, who I believe has --

MR. EISENSTAT: We are aware of this, Your Honor, and we will, you know, do our best to accommodate them. We can't guess yet how long our cross examination will be really until we hear the witnesses.

JUDGE CHAPPELL: But the person who will handle that witness will be available today?

MR. EISENSTAT: Yes. Oh, yes, Your Honor.

MR. NIELDS: And then, Your Honor, tomorrow Upsher has another witness who becomes completely unavailable after tomorrow, that's Dr. Halvorsen. So, that will be the witness for Friday, the partial day on Friday.

JUDGE CHAPPELL: Okay.

MR. NIELDS: And then we will be calling Mr. Audibert on Tuesday. As I recall, Monday is a holiday,

so our next day will be Tuesday, and that will be Mr. Audibert, and I believe he will be followed by Mr. Lauda.

JUDGE CHAPPELL: Okay, and regarding days off, we originally scheduled the 25th, and I wanted to maintain that we would have that day off, and I will -- assuming we're still in trial then, I'm hopeful we'll wrap up before then, but assuming we're still in trial -- but I would like everybody to check your schedules and see if you are available on the 25th. If not, that's okay, because we had originally blocked that one off, but we are going to have to take the 27th off. I have a commitment I have to attend to.

MR. NIELDS: For whatever it's worth, Your Honor, we have been doing some talking, and there is considerable more evidence to go on both sides, so that the 25th -- I mean, we've been trying to figure out ways of making it move quicker, but it might be a good idea if we can make the 25th a trial day.

JUDGE CHAPPELL: It's okay with me. I thought maybe you or someone had a conflict that day.

MR. NIELDS: I did have a problem, Your Honor, but I think that this may take priority.

JUDGE CHAPPELL: It's always good to hear that, Mr. Nields. Then just go ahead and let me know,

because I'm leaving it on my calendar for now that, you know, I'm -- I'm here if you people are here.

MR. CURRAN: Your Honor, you may recall it was my scheduling conflict that originally led to the 25th being an off day. I had an argument scheduled in the Fourth Circuit on Monday, the 25th, but that has been postponed. The Court granted leave to reschedule that argument in light of this proceeding.

JUDGE CHAPPELL: Right, okay. And so are you saying now you want to go the 25th or do you still need to check on your conflict?

MR. NIELDS: I probably ought to make just one final check, Your Honor. It's a case I have argument scheduled in, but I do not plan to be actually arguing it. I think my client will accept the notion that I'll be here.

JUDGE CHAPPELL: Or one of those Army from your firm could sit here for you that day. That's up to you.

MR. CURRAN: Mr. Nields won't say it, but he's irreplaceable, Your Honor.

JUDGE CHAPPELL: Most lawyers probably won't say that, but they think that. Judges too.

MR. NIELDS: But only about themselves, Your Honor, lawyers only about themselves.

Your Honor, one other thing is that there is one topic on which Schering -- that Dr. Horovitz may testify about for which Schering gave less notice than we had agreed we would give regarding documents that he reviewed.

JUDGE CHAPPELL: So, what you are doing now, you are trying to soften the normal morning bombardment that I have.

MR. NIELDS: No, I am actually not, Your Honor. I'm going to tell you we have reached an agreement.

JUDGE CHAPPELL: Excellent.

MR. NIELDS: And the agreement is that if we decide that we need to go into that topic, we can bring Dr. Horovitz back that -- it will be a week, because he will be away every day in between, but we may bring him back next Thursday to cover this one topic.

JUDGE CHAPPELL: And as I said early on, we are going to have a record, and all these witnesses are going to be in there somewhere. I'm going to dig them out, and it's up to you all to point out to me in your post-trial briefs.

And I think I said earlier but I'll re-emphasize, you should probably get busy on those, and I am going to need valid proposed findings of fact and conclusions of law with record cites, cites to the

record and to exhibits. That's the only way it will help me out.

MR. NIELDS: We have taken that to heart, Your Honor.

JUDGE CHAPPELL: I just wanted to re-emphasize, because the date for the initial decision is drawing closer and closer.

So, with that, anything else?

MR. NIELDS: No, Your Honor, thank you very much.

JUDGE CHAPPELL: Let's proceed.

MR. CURRAN: Your Honor, for Upsher-Smith, Mark Gidley will be handling this witness.

JUDGE CHAPPELL: Okay, thank you.

Have you got a witness?

MR. RAOFIELD: Schering-Plough calls Zola Horovitz, Your Honor.

JUDGE CHAPPELL: Raise your right hand, please.

Whereupon--

ZOLA P. HOROVITZ

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, be seated.

Sir, state your name for the record, please.

THE WITNESS: Zola Horovitz, H O R O V I T Z.

JUDGE CHAPPELL: You might want to spell your first name.

THE WITNESS: Zola, Z O L A.

JUDGE CHAPPELL: Thank you.

MR. RAOFIELD: Your Honor, I have distributed copies of a thin binder, I see that you have already located that, and everyone already has a copy of that as well, including the witness.

JUDGE CHAPPELL: I see he has his water bottle, so I think we're ready. Go ahead.

MR. RAOFIELD: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. RAOFIELD:

Q. Good morning, Dr. Horovitz.

A. Good morning, Mr. Raofield.

Q. Where do you live, Dr. Horovitz?

A. In Boca Raton, Florida.

Q. And what is your profession?

A. I'm a consultant in the biotechnology and pharmaceutical field.

Q. Dr. Horovitz, I'm going to ask you about your education and employment history. Have you prepared a slide that will assist in quickly bringing us through your educational history?

A. Yes, I have.

Q. I will put that on the screen now. Is this the slide you prepared?

A. Yes it is.

Q. Can you briefly describe for us any graduate or postgraduate degrees you've received?

A. Yes, I have a Bachelor's in pharmacy and a Master's and Ph.D. in pharmacology, the science of how drugs work, all from the University of Pittsburgh, and I did a post-doctoral fellowship at the Squibb Institute for two years before I became a full-time member of the Institute.

Q. And could you briefly take us through your career in the pharmaceutical industry?

A. Yes. After doing research as a post-doc fellow and then a member of the pharmacology department at Squibb, I became director of that department in 1967, and one of the assignments was to form a cardiovascular group, which I did, and that group later led to the discovery of the angiotensin converting enzyme inhibitors, the first -- Captopril, the first drug for Squibb to be a billion dollar drug and I think the second billion dollar drug in the industry.

Q. Before you go on, Captopril, what is that drug used to treat?

A. That treats both high blood pressure and

congestive heart failure.

Q. And you can continue with the next.

A. Yes, then in '72, I became associate director of the Squibb Institute, which -- the Squibb Institute, I should say, was the research and development arm of the Squibb Corporation, and then in '79, VP of R&D, moved over in '81 to be vice president of drug development, and during that reign, I had responsibility for groups that worked with the manufacturing part of the company.

And then in 19 -- approximately 1986, I assumed a new role for the company, VP, research planning and scientific liaison. The reason for that new role was that the company felt that the research people and the business people, marketing, sales, et cetera, were not communicating well, which was classic, I think, in the industry, and it was my responsibility to make sure the rest of the company knew what research was doing and that research knew what the rest of the company was interested in.

In 1989, Squibb and Bristol merged, and at the time of the merger, I was appointed vice president of licensing, a year later added business and commercial development, and also -- it doesn't say there, but I had a strategic planning group for the corporation.

And then in 1994, I accepted an early retirement package from Bristol, and since 1994, I've been consulting in the industry and serve on a number of small to medium biotech or pharmaceutical company boards.

Q. Dr. Horovitz, have you published any articles or books?

A. Yes, I believe approximately 60-some articles or chapters in books.

Q. And are you a member of any professional associations?

A. Yes, a number. The Licensing Executives Society, the Pharmacology Society and many, many more.

Q. And have you held any teaching positions?

A. I have had adjunct teaching positions at Rutgers Medical School, Rutgers Pharmacy School, the University of Pittsburgh Pharmacy School and Princeton University.

Q. Dr. Horovitz, during your career, have you received any awards?

A. Yes. There were I guess three I could comment on. One was in -- when I was doing research in the early sixties, received the A. E. Bennett Award for Research in Biological Psychology, I believe I was the first industry person to get that award. In the

seventies, I believe I was awarded a Distinguished Alumnus Award from the University of Pittsburgh. And in the early nineties, my team and I at Squibb who discovered the angiotensin converting enzyme inhibitors won the American Heart Discoverer Award.

Q. During your career in the pharmaceutical industry, Dr. Horovitz, roughly how many licensing or technology transactions would you say you have been involved with?

A. Well, it would be a very rough answer, but I would say in a range of 75, plus or minus.

Q. And did any of those involve the in-licensing of a cholesterol-lowering drug?

A. Yes.

Q. And what drug was that?

A. That was a drug called pravastatin or the trade name for Squibb and later Bristol-Myers Squibb was Pravachol. That was the second discovered statin for lowering cholesterol, affecting an enzyme which causes a lowering of cholesterol.

MR. RAOFIELD: Your Honor, at this time we offer Dr. Horovitz as an expert in the pharmaceutical industry and licensing and evaluation of pharmaceutical projects.

JUDGE CHAPPELL: Objection?

MR. EISENSTAT: No objection, Your Honor.

MR. GIDLEY: No objection, Your Honor.

JUDGE CHAPPELL: Okay, thank you. Hearing no objection, he's accepted.

BY MR. RAOFIELD:

Q. Dr. Horovitz, have you been retained to offer an expert opinion in this case?

A. Yes.

Q. And by whom were you retained?

A. By Schering Corporation through Howrey law firm.

Q. When were you retained by Schering?

A. I believe it was early summer of 2001.

Q. Now, at that point, what opinions were you asked to render?

A. First, upon being retained, I was asked to give an opinion on the value of a deal done between Upsher-Smith and Schering back in June of 1997 to try to determine what the value to Schering would be for doing that deal.

Q. And did there come a time when you were asked to render subsequent opinions?

A. Yes, after I did my first report, first opinion, I was then given more material and asked to opine on a report by Dr. Nelson Levy, who was an expert

witness in the case, and comment on a number of issues that he raised in his report.

Q. And are you prepared to testify as to your opinions here today?

A. Yes.

Q. Dr. Horovitz, you referred to two parts of your opinion. Would it be okay with you if I referred to them as part one of your analysis and part two of your analysis?

A. Correct, I believe that's what I did in the full report, yes.

Q. With respect to part one of your analysis, what materials did you rely on in forming your opinion?

A. The only thing I received was a redacted contract. The redactions were the up-front payments for the deal, so I did not know that; a commercial analysis I believe done by Mr. Audibert; and a copy of a document that looked like it was a slide presentation -- I'm sorry -- that was presented from Upsher-Smith to Schering-Plough concerning Niacor-SR; and a couple documents referring to a product called Niaspan from Kos Pharmaceutical Company, I believe one was an S-1 that supported their IPO and then a couple of analysts' reports on their product, Niaspan. And I think that was all I received before I finished my

phase one.

Q. Based on your review of those materials, did you form any opinions?

A. Yes, I did.

Q. And have you prepared a slide to help you briefly take us through those opinions?

A. I believe so.

Q. The slide that I've put on the screen, is that the slide that you had prepared?

A. Yes.

Q. Now, Dr. Horovitz, could you briefly explain the conclusions that you've reached? And I'll ask you to begin with the bullet point number one there.

A. Yes, before you can do a value on any project, you have to look at hopefully a good P&L assessment, and what makes up a good P&L assessment are the assumptions. If the assumptions are no good, the numbers are no good. So, I looked at the assumptions and thought that they were reasonable and properly conservative for the information that was available at that time.

Q. And the second bullet point listed here, could you explain that?

A. Yes, there was a royalty provision in the agreement, which I did see the royalty provision,

between 10 and 15 percent, depending on the sales, and for a drug like Niacor-SR, which was very close to filing and hopefully approval, those were reasonable royalty rates in the industry at that time.

Q. And finally, the third bullet point?

A. I did an analysis of the value, both the internal rate of return and net present value of this project based on the P&L statement, and I concluded that Schering could have paid up to $100 million for -- up front for the Niacor-SR and still obtained a reasonable return on its investment.

Q. I'm going to put a single-page document up on the ELMO. Give me a second here just to try to make this...

For the record, this document has been marked for identification as SPX 2240, and fortunately I have a couple of additional copies of this, so if anyone has difficulty reading --

A. Is that in my binder, because I can't --

Q. This one is not in your binder, no, Dr. Horovitz.

A. Okay, I'll need a copy.

MR. RAOFIELD: Your Honor, may I approach the witness?

JUDGE CHAPPELL: Yes.

THE WITNESS: Thank you.

JUDGE CHAPPELL: Thank you.

BY MR. RAOFIELD:

Q. Dr. Horovitz, a moment ago you were discussing the third bullet point on your part one analysis slide, and you made reference to the calculations you did to conclude that Schering would have paid up to $100 million for Niacor-SR.

A. Correct.

Q. The document that I've handed you and that I've put up on the screen, SPX 2240, are those the calculations that you performed?

A. Yes, this looks like a copy of the table that I attached to my part one report.

Q. Now, the document is entitled Internal Rate of Return and Net Present Value Analysis. Could you explain what net present value is?

A. Well, for a ten-year period, I did a cash flow projection and determined the value to Schering in millions of dollars for doing this deal based on a number of different up-front payments, because I did not know at the time what the actual up-front payment was. So, I arbitrarily took a range from $12 and a half million up to $100 million as the up-front payment and then calculated the value to Schering, and those

are the numbers you see at the bottom, for each of those dollar payments.

Q. And generally, not specific to your calculations here, what is the purpose of a net present value analysis calculation?

A. Well, it's to get an idea of what the project will return as far as profit to -- and cash flow to the company.

Q. Now, turning back to the document again, towards the bottom, next to where you have net present value, I see a 10 percent number. Could you explain what that refers to?

A. Yes, that's a discount value. I used a 10 percent discount. Whenever I did net present values, I always used some discount value, unless the project is already on the market, because there is some risk to the capital that you're going to invest. If this drug was in an early phase of development, I would have used a higher discount value. In this case, something that's near, very near filing with a regulatory body, I generally would use about 10 percent.

Q. And you said that when a drug is earlier in development, you'll use a higher discount percentage. Why would you use a higher discount percentage?

A. Because there's more risk. There's more risk

to you actually obtaining that pay-back, that amount of money, because there's chances the drug will be delayed or fall out of bed.

Q. Dr. Horovitz, could you explain now what internal rate of return is?

A. Yes, that's the percent return on their money for the investment. Here, with each of these projected possible payments, which represented most of the money Schering would expend to get this drug on the market, you want to know what the return is on them making that investment. They can take their $100 million, let's say it's $100 million, and invest it in secure treasuries or something like that and get a certain return.

In this case, we determined that if this project went the way it was planned, they could get a return of 35 percent on that $100 million, and most of the pharmaceutical companies I'm familiar with, they would be very happy with that return.

Q. At the time that you made these calculations, did you make any assumptions as to how the payments would be made over time for each of these various scenarios?

A. Well, no, I knew from reading the redacted document that the payments were spread out over two

years, though I didn't know what they were, but I felt for ease and lack of complexity that I would just make it that Schering would pay all of these up front. Obviously, if the total payment would be spread over two years, these numbers would look better to Schering, because they would have use of their money for two years -- some of their money for two years, and it would be a better return. But -- so, I used a conservative approach of just everything being paid at the signing of the agreement.

Q. It appears that you -- I think you testified you have five payments that you selected, and we don't have to go through each one, but taking a look, for example, at the $50 million payment?

A. Correct.

Q. What did you calculate the net present value and internal rate of return on a $50 million payment would be?

A. The net present value at a 10 percent discount would come out to about $255 million, and the internal rate of return, about 56 percent.

Q. And with the $75 million payment at signing?

A. The net present value was $230 million and the internal rate of return was about 43 percent.

Q. And the $100 million payment at signing?

A. Was $205 million for $100 million payment, and internal rate of return, 35 percent.

Q. Dr. Horovitz, with respect to the $100 million payment, do you have an opinion as to whether an internal rate of return of 35 percent is a reasonable return on that investment?

A. Yes, as I said, most pharmaceutical companies would be happy with an internal rate of return of 35 percent on their money.

Q. And Dr. Horovitz, during your part one analysis, did you reach any conclusions as to what would have been a reasonable payment for Schering to make for the rights to Niacor-SR as those rights are provided for in the Schering-Upsher agreement?

A. Yes, in my report I indicate that I believe that certainly up to $100 million as an up-front payment would have been a good return for Schering on this deal.

Q. And Dr. Horovitz, at the time that you reached that opinion, did you have any information regarding the amount of the up-front and milestone payments that Schering had actually agreed to make for that product?

A. No.

Q. We're done with that document, you can put that one aside.

Now, you mentioned, Dr. Horovitz, that there were two parts of your analysis, and again, I think you said it would be okay, would it be okay if I referred to part two as your part two analysis?

A. Correct.

Q. Could you briefly describe what opinions you were asked to render after you had completed part one of your analysis?

A. Well, in summary, I was given -- after my part one analysis was done, I was given Dr. Levy's expert report and some other documents, some deposition transcripts, and asked to comment on issues that were raised by Dr. Levy in his report.

Q. Did you consider any additional materials in forming your part two opinion?

A. Yes, quite a few.

Q. And what types of materials?

A. Depositions, the expert reports, literature, which I looked up, PDR, labeling for drugs, and obviously memos and documents that related to some of the issues that Dr. Levy mentioned.

Q. You may have mentioned this, but I'm not sure I heard it. Did you review any depositions?

A. Yes. Yes, I did.

Q. On the basis of those materials, did you form

any opinions?

A. Yes.

Q. And have you prepared a slide to assist you in briefly outlining your part two analysis?

A. Yes.

Q. I'll put that slide up on the screen now.

Is this the slide that you prepared, Dr. Horovitz?

A. Yes, um-hum.

Q. Now, it appears that there are five bullet points. Beginning with the first bullet point, could you briefly describe what that refers to?

A. Well, in my report, I pointed out that niacin, although originally discovered as a vitamin, had been shown to lower cholesterol and have a profile of lowering cholesterol that was probably better than any other type of drug around. It did the right things. It lowered low density, the bad cholesterol; it lowered triglycerides; it lowered Lp(a), a protein, Lp, little (a), which people believed was responsible for some of the clogging of the arteries in the heart and vessels; and it raised HDL, the high-density lipoproteins or the supposedly good lipoproteins. So, it had a good spectrum of action.

However, it had problems. Some of the side

effects were somewhat debilitating, especially the side effect of flushing, which is essentially part of its pharmacology. Niacin will cause the peripheral vessels to dilate and the redness -- in some people the redness and the itching that occurs with that pharmacological effect is -- bothers people, and they stop taking the drug, which, of course, isn't good for their therapy.

Q. Okay. And with respect to the second bullet point, could you just briefly describe -- we will come back to it later -- but could you just briefly describe what your bullet point refers to?

A. The second one?

Q. Yes.

A. Well, in the mid-1990s, it was hoped that a sustained release formulation of niacin would solve some of the problems of the flushing side effects and yet still give you good efficacy for lowering cholesterol and you would have a much better product.

Q. And what are you referring to as market opportunity?

A. Well, a couple things. One, the statins at that time were really taking hold in the marketplace, but physicians felt in a number of patients they needed something else to -- to add on to the statins to really get the kind of control they wanted.

And secondly, there apparently was a market opportunity for the SR niacin, and that relates to what this company Kos was doing with a formulation of sustained release niacin. They had formed a company. Their major product was the SR niacin called Niaspan, and they had a lot of stock analysts doing projections on excellent sales for that product, and they also did an IPO, initial public offering, which the marketplace and investors put in a large amount of money primarily because they felt that Niaspan was going to be a good product for Kos.

Q. And the next bullet point is, "Niacor-SR Product Profile."

What was the purpose of that part of your analysis?

A. Yes, the purpose there was to look at Niacor-SR. Dr. Levy had made some major comments about the -- both the efficacy and side effect profile, and I analyzed the data that was known to Schering in June of '97 and determined it had an efficacy profile that was certainly sufficient to treat patients and get approval and a better side effect profile, especially on flushing, than the previous Niaspan product -- I'm sorry, previous niacin products.

Q. And the next bullet point refers to, "Strategic

value Niacor presented to Schering."

Again, without going into detail, could you just state what the purpose of that part of your analysis was?

A. Well, briefly, any pharmaceutical company in the mid-nineties was very interested in the lowering cholesterol market. This market was really taking off because of the statins. Schering I found out had a new mechanism product for lowering cholesterol called ezetimibe in their research pipeline, and I think strategically, it was very important for them to get into this field, to have their sales force, their marketing people and all their executives experienced and knowledgeable in the cholesterol-lowering field before they would be introducing ezetimibe, a novel new type of cholesterol-lowering agent, some years later.

Q. And finally, the last bullet point, what was the purpose of that part of your analysis?

A. Yes, this was just a more detailed look at the assumptions supporting the P&L that was given to Schering's board to approve this project, and by more detailed, I mean I now was able to look at more documents than I had in my phase one report.

Q. I'd like to turn now to -- the first bullet point that you have there is the immediate and

sustained release niacin generally, and beginning with that, could you tell us what was known in the early to mid-1990s about the efficacy of niacin generally?

A. Yes, niacin, as I think I said, was a very good agent for giving you the right cholesterol profile, lowering the right things and raising HDL, but it had side effects, like flushing, which were something that kept its usage down.

Q. When was niacin discovered to have the efficacy profile that you just described?

A. Oh, I'm not sure I remember exactly.

The other thing, of course, that happened with niacin, it was used in some large clinical trials on patients with heart disease, and it was shown to decrease significantly the morbidity and mortality of patients with heart disease. So, this was a clinical effect that niacin was proven to have, which was, of course, very beneficial to the patient.

Q. Well, a moment ago you had referred to efficacy in terms of altering the lipids in the blood.

A. Yes.

Q. And now you're referring to what you called morbidity and mortality. Could you explain the difference between those two?

A. Sure. This measure in cholesterol is called a

surrogate marker. It means I'm using the cholesterol levels as a marker to say I believe -- excuse me -- I believe that doing that is going to benefit the patient, but just lowering cholesterol doesn't mean it benefits the patient. You really want to be able to show that lowering cholesterol correlates with the patient having fewer heart attacks, having better flow in its -- in his or her arteries, et cetera, et cetera. That's a clinical outcome.

So, preventing heart attacks, having better blood flow, taking a debilitated cardiovascular patient back to work, that's -- those are clinical outcomes, and the data supported the fact that using niacin and later on using the statins, lowering cholesterol correlates with that better clinical effect.

Q. Now, Dr. Horovitz, given that niacin generally was recognized as an effective anti-cholesterol drug as you've testified, was it experiencing widespread use in the marketplace in the early to mid-1990s?

A. It was used, but I would not call it widespread, and I think the reason was as I said, that the flushing, especially the itching side effect, prevented its widespread use.

Q. And can you just describe what flushing is?

A. I think I did before. It's a vasodilatation

that is part of the pharmacology of niacin, and it -- niacin will vasodilate almost every patient, but some get a response of the blood flowing quickly to the periphery, and you see the redness, flushing, and some of these patients also get itching because of that.

Q. Now, Dr. Horovitz, in addition to Niacor-SR, are you familiar with an additional product referred to as Niaspan?

A. Yes.

Q. And do each of those products, Niacor-SR and Niaspan, have niacin as their active ingredient?

A. Yes, those are both products that have niacin in a controlled release dosage form.

Q. And did each of those products -- were -- so, each of those products were sustained release you just said. What was the significance of the sustained release form of those drugs?

A. Well, it was hoped -- sustained release technology was developed with the hope that they could take drugs that had either efficacy or side effect problems and by controlling their release improve on their efficacy and also decrease side effects.

Q. I'm going to ask you to explain how the sustained release technology was designed to overcome the flushing side effect, but I'm going to ask you to

put aside Niaspan and Niacor and refer to just sustained release niacin generally.

Have you prepared a slide to assist you in explaining that?

A. Yes, I have.

Q. What I've put on the screen there, is that the slide that you had prepared?

A. Yes.

Q. Using this graph, could you briefly explain how the sustained release technology was used to reduce the flushing side effects?

A. I'll try. Below we're plotting hours, it's a 24-hour day, and actually the label for the other ordinate isn't there, but it's blood -- it's essentially blood level. So, if you look at the regular niacin, which is called IR niacin, internal release niacin --

Q. And that's the red line?

A. That's the red line, and we've arbitrarily here said we're going to give this patient one tablet three times a day, and you can see the blood level rises pretty rapidly, goes up to a peak, high peak, and then returns, and then eight hours later you give another drug, and that same curve shows up.

With the SR, the formulation delays the release

of the product into the bloodstream so that there is a different kind of curve. It goes up more gradually, its peak -- the blue, we're now talking about the blue dashed line -- its peak is much lower, and it returns and you lose efficacy threshold much longer.

Now, arbitrarily, I took what might be called the flushing threshold, i.e., a blood level above which you get a lot of flushing and it becomes a problem for the patient, and I took an efficacy threshold, and you can see with the red, the IR, the immediate release niacin, you get certainly efficacy, but you also get a lot of time when the -- you're well above the flushing threshold. That is not the case with the SR, where you are a longer period of time in the efficacy threshold but very little above the flushing threshold.

So, the design is to keep or prolong efficacy and decrease a side effect that might be related to high blood level peaks.

Q. Now, aside from Niaspan and Niacor-SR, had any other companies tried to use the sustained release technology to overcome the flushing side effect experienced with immediate release niacin?

A. Yes, I believe there were a few in the earlier nineties, but none of them ever were studied towards an NDA approval, so it's hard to gauge how effective or

how good they were, but there were some available in the over-the-counter market.

Q. Now, aside from the flushing, were any of those prior sustained release versions of niacin associated with any additional side effects?

A. Yes. There -- they were associated in some literature with an increase in liver function enzymes.

Q. Now, you said they were associated in the literature, I believe?

A. Yes.

Q. Could you give us an example of a published study which associated sustained release niacins with elevated liver enzymes?

A. Yes. There -- the main article, which unfortunately was referred to many, many times afterwards, was an article by McKenney in the Journal of the American Medical Association, where he studied a product that was a sustained release niacin product from a company called Gold Line, and he had a high percentage of patients who had increased liver function enzyme values. I think 60-70 percent of his patients did.

He then did a literature survey and found a couple of other studies with sustained release niacin that indicated some hepatitis with -- in a few

patients. He concluded -- and, you know, that was all fine. Unfortunately, his conclusion was that all SR niacin products were hepatotoxic, which was definitely not a conclusion he could make from the data he had.

Q. Dr. Horovitz, what is hepatotoxicity?

A. Yes, hepatotoxicity is a toxicity of the cells in the liver. When liver cells are stressed, they will tend to break up a little bit, and enzymes will be released, and that's why liver function enzyme measures in the blood are an indication that the liver is being stressed. They're not necessarily an indication of hepatotoxicity. Hepatotoxicity will occur if enough of the liver cells are stressed, but liver function tests can go up for a number of reasons.

Q. So, there's a distinction you're saying between one and the other, between hepatotoxicity and elevated liver enzymes?

A. That's correct. To say it again, to be clear, liver function elevations are an indication that the liver has some stress. Hepatotoxicity may result, and it's certainly something to think about if you get increased liver function tests, but there are a number of things that can cause it.

Q. What does -- what significance, if any, does that distinction have when evaluating the side effects

of cholesterol-lowering drugs?

A. Well, it's -- all cholesterol-lowering drugs, I believe, will cause some increases in liver function tests in some patients, and I believe they all have labeling that indicates that periodically, the physician should take a blood sample and have that sent to the lab and tests done for liver function -- I'm sorry, for liver enzymes.

If the liver enzymes are continuously high or going up to dangerous levels, then, of course, the physician should stop the drug before anything further happens to the liver. That happens in a small percentage of patients with a number of drugs, not only cholesterol-lowering.

Q. Now, when you refer to liver enzymes, is there one type of liver enzyme or are there multiple types of liver enzymes?

A. Well, most of the time the measures are what is called ALT, alanine transaminase, and AST, aspartame transaminase. There are other liver enzymes that you could measure, but those laboratory tests are very difficult. The ALT and AST are easy to measure now for most outside laboratories, and it's a fast test, a relatively cheap test, and that's what's used by many.

Q. Is a shorthand way to refer to ALT and AST

collectively to refer to them as LFTs, liver function tests?

A. Yes, we can do that.

Q. And would that be okay, if when I refer to LFTs or liver function tests, you just assume that I am referring to ALT and AST?

A. That's fine.

Q. In reaching your opinions in this case, was there any particular level of elevation of LFTs or liver function tests that you viewed as relevant?

A. Well, the -- for a long time, the Food and Drug Administration has set criteria at three times the upper limit of the normal range for the laboratory. So, if the laboratory's upper limit -- and by upper limit and lower limit, I mean the variation, because there is variation in these tests. You don't always get the same number from the same sample. So, if you do the same sample a number of times, you'll get a range.

So, let's say that range is somewhere between 15 and 20, 20 is the upper limit, and so if you go three times that, it's 60. That's a sign that you better consider maybe stopping the drug for a while or switching to another drug or something like that.

Q. Now, in the real world, if a physician is

treating a patient with a cholesterol-lowering drug and the patient experiences liver enzyme elevations of three times the upper limit of normal, what might the physician do to address that situation?

A. As I said, he would probably stop the drug. He might then restart it, and sometimes it never goes up again, or he may switch to a different drug in the same class, say if it's a statin to another statin, or he may switch to a different mechanism drug, a niacin or a fibrate or one of the other ways of lowering cholesterol.

Q. And will a physician -- at that point, does the physician conduct multiple measures or single measures or --

A. Well, he should at least wait until he has two tests, because there is not only a variation in the laboratory, there are cases where laboratories have shown large spikes in liver enzyme tests, and then it never happens again. So, it's a one-time phenomena, it could have been a mistake in the lab, could have been the patient was heavily exercising or drinking alcohol right before the test.

So, you usually -- it's recommended that you do two tests, and if both tests are high, above three times upper limit of normal, then that should be a

warning to the physician.

Q. Dr. Horovitz, are drugs the only thing that can cause elevated liver enzymes?

A. No, as I just said, that alcohol use can, severe exercise can, other drugs, concomitant drugs like aspirin can, and, of course, disease like cirrhosis or hepatitis can, and the liver enzyme changes could be an indication of a disease process having nothing to do with a drug.

Q. Now, you referred a moment ago to the FDA using three times the upper limit of normal, and my question is whether you've seen any evidence in this case with respect to the Niacor-SR clinical studies that would support your conclusion that that would be the relevant standard.

A. Well, I believe that that is the standard they used for stopping treatment in their protocols, in their two pivotal trials.

Q. I'm going to refer you to a document in your binder marked SPX 267. I believe it's actually the last one in the binder based on the numbering.

Dr. Horovitz, do you recognize this document?

A. Yes, I've seen it.

Q. And what does this document show -- tell you that's relevant to your analysis?

A. It's a telephone communication record between Upsher and the FDA, and the response from the FDA in the second page indicates that they stated that the FDA considers liver function tests equal to or greater than three times the upper limit of normal on two occasions to be of clinical significance, and they ask for really -- their analysis to be two groups, one the -- any patient who was two times the upper limit of normal and above and any that were three times the upper limit of normal or above.

Q. And is that the passage that I just highlighted and put up on your screen?

A. Yes. That and the next sentence, too.

Q. And the next sentence as well.

And Dr. Horovitz, a while ago you referred to studies that were published in the 1990s, I believe you referred to one in particular. Again, what was the product tested in that study?

A. Are you referring to the McKenney study?

Q. I believe that's the study that you referred to. You can correct me if I'm wrong.

A. Yes. It was a sustained release product according to the report made by a company called Gold Line, which at that time was a generic pharmaceutical house.

Q. And that was a sustained release niacin product?

A. That's what they claimed, yes.

Q. Do you recall whether that study indicated what percent of patients experienced liver enzyme elevations at three times the upper limit of normal?

A. I recall that it was very high, 60-70 percent range.

Q. Dr. Horovitz, are you aware of the level of elevation that Dr. Levy, complaint counsel's expert, considered relevant in evaluating the incidence of liver enzyme elevations in this case?

A. Yes, I believe he considered anything above 1.5 times the upper limit.

Q. And do you agree with Dr. Levy's consideration of the elevation of liver enzymes above 1.5 times the upper limit of normal?

A. No.

Q. And why not?

A. Well, most studies will allow patients into the study if they have something like 1.2, 1.4, maybe up to 1.5 times the upper limit of normal. So, if you use Dr. Levy's criteria and you have patients who are entered very close to that criteria already, just a slight laboratory change can throw them into being --

into being rejected or to, you know, be taken off the study medication.

Q. Actually, I'm just going to flip this over if I could and write on the back of this.

You referred earlier to what you said you would just assume for your argument was 15 to 20 was the normal range.

A. Okay.

Q. And these -- that would refer to the laboratory value as opposed to a specific level of elevation, correct?

A. That's laboratory values that are normal, meaning that lab had done a lot of testing of the same sample, and the range almost always -- the result almost always came between that 15 and 20.

Q. And in your previous answer when you were talking about the inclusion/exclusion criteria at 1.5 times the upper limit of normal, what would -- what level could a patient, if you were to assume that the laboratory at that time was using a range of 15 to 20, what level could a patient enter a study and still be below the 1.5 times the upper limit of normal?

A. Well, if my math is right, that means 30 would be 1.5 times the upper limit at this level.

Q. So, a given patient could enter the study with

let's say a laboratory value of 29. Is that correct?

A. And be accepted in the study, correct.

Q. And I seem to be writing a little bit too big, so let me back up and try to fit it on the screen.

Now, if the patient experienced during the course of the study an elevation to, let's say, 31, would that patient have now experienced an elevation? And I did it again here, let me just -- would that patient have now experienced an elevation? Having gone from 29 at the time of entry of the study to 31 during the course of the study, would that patient have now experienced an elevation to 1.5 times the upper limit of normal?

A. That patient would be over that criteria.

Q. And do you consider it significant that a patient would experience an elevation from 29 before entering a study or before beginning taking a drug to 31?

A. No, I think that's well within the limit of normal variation.

Q. Even though that patient is now above 1.5 times the upper limit of normal?

A. That's correct.

Q. Dr. Horovitz, I believe we've now covered -- I've put back up on the screen the slide that you had

used to outline your part two analysis, and I believe that we've now covered the first bullet point, and I would like to move us now to the second bullet point you identify on here, "Market Opportunity for an SR Niacin in the Anti-Cholesterol Market as of June of 1997."

Could you briefly -- when you performed this part of your evaluation, what was the purpose?

A. Well, the purpose was to look at whether Niacor-SR was a reasonable drug for Schering to consider, i.e., was there market opportunity for that product at that time.

Q. And did you reach any conclusions?

A. Yes.

Q. And what conclusions did you reach?

A. My conclusions were that it was a reasonable product, that there was a need for a different type of niacin product in the marketplace, and there was a need for a different mechanism than the statins in the marketplace at that time.

Q. And I believe earlier in referring to part one of your analysis you said that some of the documents you relied upon related to a company called Kos Pharmaceuticals. Is that correct?

A. That's correct.

Q. And did those documents relate to this part of your analysis?

A. Yes.

Q. And how did they relate to this part of your analysis?

A. Well, Kos had been developing this product called Niaspan, which is a sustained release niacin product, and they had a lot of information on their product, although it wasn't available in great detail. They had done market research. In their S-1 document for their IPO, they described what they thought the marketplace was. Analysts, since the product was late stage, analysts had picked it up, and those analysts that followed Kos were projecting a marketplace for their sustained release niacin in the U.S. only.

And I think that information and, as I said before, the fact that the public and the bankers were supporting investing a lot of money into Kos indicated that there was major interest in a niacin SR product at that time.

Q. Moving now to the third bullet point that you have here, the "Niacor-SR Product Profile," and then below that you have got two subpoints, "Efficacy Profile" and "Side Effect Profile."

A. Um-hum.

Q. What was the purpose of that part of your analysis?

A. Well, as far as efficacy, I wanted to make sure that the data available would indicate that Niacor-SR could be approved by any regulatory body, and if you look at the Food and Drug Administration criteria, they wanted the pivotal studies on a niacin SR drug to show at least a 15 percent decrease in LDL, and indeed, that's what the data of the Upsher-Smith study showed.

Q. What information did you review in this part of your analysis?

A. This was the documentation that Upsher-Smith provided Schering on the two pivotal studies, I think it's 115 and 221. One combined a -- one compared the drug at different doses to an immediate release niacin, and the other study compared different doses to the -- to a placebo.

Q. And for the record, in your binder, is the document you're referring to -- I believe it's actually the first one there, CX 1042?

A. Yes, that's it.

Q. And is it your understanding -- do you have an understanding one way or the other as to whether or not this document was provided to Schering in June of 1997?

A. Yes, my understanding, that it was received in

early June of '97.

Q. Dr. Horovitz, what did you conclude with regard to the efficacy of Niacor-SR?

A. That it lowered LDL, triglycerides and Lp(a), and it raised levels of HDL.

Q. Do you recall what doses were tested in the Niacor-SR pivotal studies?

A. Yes. The IR study -- the immediate release study compared 1000, 1500 and 2000 milligrams, and I believe the placebo study was 500, 1000 and 2000.

Q. Do you recall what the data showed with respect to the efficacy in reduction of LDL with respect to the 1000, 1500 and 2000 milligram doses?

A. Well, I don't know the exact numbers, but looking at the 15 percent criteria, it was more than 50 percent decrease -- more than 15 percent decrease at 1500 and 2000. I'm not sure the 1000 reached that criteria. It was close, but it didn't make it.

Q. Now, does that -- if the 1000 didn't reach that criteria, does that mean the 1000 milligram dose was not effective in lowering LDL levels in any of the patients?

A. No, not at all.

Q. And why doesn't it mean that?

A. Well, that's an average decrease from all the

patients in the study. So, some of them I'm sure were slightly higher, a number lower than the 15 percent, but even if it was only lowered 10 percent in some patients, that could be significant.

Q. Dr. Horovitz, focusing on the 1500 milligram dose and the 2000 milligram dose in the Niacor-SR pivotal studies, did you reach any conclusions as to a comparison of the efficacy of those two doses? And I'm talking now not specifically LDL but all of the lipid parameters.

A. Which two, the --

Q. The 1500 milligram and the 2000 milligram dose.

A. Yeah, as I remember, they were pretty equivalent. The 2000 was a little more potent, but there wasn't a significant difference among the two.

Q. Now, returning to the side effect profile that you identified on your slide, what if you -- what, if anything, did you conclude about the flushing side effect with Niacor-SR in the pivotal studies?

A. Well, it was clear from the 115 study, I believe, that the SR product had significantly decreased the amount of flushing. It didn't eliminate it but significantly decreased it from the immediate release product.

Q. Now, as with the efficacy, is the data that you

relied upon in forming that conclusion part of the document CX 1042?

A. Yes.

Q. And did you prepare a slide to help you explain the data that you relied upon in reaching this conclusion?

A. Yes.

Q. I've put a slide up on the screen. Is this the slide that you're referring to?

A. I believe so, yes.

Q. Just generally, to begin with, could you explain what the data on the slide represent?

A. Well, it compares from the 115 protocol and study the results from four groups. Group A is the immediate release niacin product. Groups B, C and D are sustained release at different doses, the 1000, 1500 and 2000.

Q. And beginning with that top line there, it says, "Average number of flushing episodes per patient."

By the way, before I turn to that, let me just state for the record that within CX 1042, and as indicated, I think, at the bottom of the slide on the screen, this data are pulled from the Bates number SP 1600089.

Dr. Horovitz, the first row there is identified as, "Average number of flushing episodes per patient," and could you explain the significance, if any, of that to your conclusion?

A. Well, they looked at each patient, how many flushing episodes during the trial, and then just got an average, and I think it's clear that they've decreased the average number of flushing episodes in this study by at least four to five fold from the immediate release product.

Q. And we don't have to, again, go through all of these lines that you've listed here, but, for example, turning to the average -- or the average percent of patients -- the line is, "Patients with greater than 100 flushing episodes."

A. Um-hum.

Q. Could you explain the significance of that line to your conclusions, if there is any?

A. Well, once again, if you just take a cut as to in the whole study how many patients had more than 100 flushing episodes, you can see 50 percent with the IR, the immediate release product, and down in the range of 10 percent or below with the sustained release product.

Q. And how about the other line I guess we can take a look at, it's the next one, "Patients with

greater than 200 flushing episodes." What's the significance of that one?

A. Yes, here the IR showed 30 patients who had greater than 200 over the test period and 1 percent or 2 percent with the SR.

Q. And so the record is clear, when you said 30 patients, did you mean 30 percent?

A. Thirty percent, I'm sorry, 30 percent of the patients in the trial.

Q. Dr. Horovitz, have you reached any conclusions about whether the flushing with Niacor-SR was sufficiently reduced such that Niacor-SR met the product opportunity of an SR niacin you identified earlier?

A. Well, I think my conclusion is that there is significant decrease, although not elimination, of the flushing episodes and that the tolerance -- the tolerance for the patient would be much better and thus more patients would stay on their regimen and use the product than would use the immediate release product.

Q. Now, before moving off of the flushing data that you reviewed for Niacor-SR, I'm going to ask you if you're able to reach any conclusion in terms of making a comparison of the flushing data that you've seen for Niacor-SR as to the flushing data for Niaspan.

A. No, because there was never a comparison in the same study, so you can't really compare I believe -- from what I know about Niaspan, it was given only once a day, it was given at different times, usually at bedtime, and unless you did a back-to-back comparison, I don't think you could really learn anything by trying to make that comparison.

Q. With that caveat in mind, if you were asked to make that comparison, would you be able to reach any conclusion?

A. No -- well, yes, you could probably reach a conclusion that the two SR niacin products were better than the immediate release, but as to the comparison, no, I couldn't make any conclusion.

Q. Finally, for -- well, before I bring the slide back up, you had underneath the Niacor-SR product profile identified the efficacy profile and the side effect profile. Underneath the side effect profile, I'd like to turn your attention to the reduction of liver enzyme elevations and ask you if you reached any conclusions about that.

A. Well, the conclusion -- I'm not sure of your question, but the conclusion I reached was that yes, there are, as one would expect with a lipid-lowering agent, there are certain -- a small percentage of

patients who have increase in liver functions.

Q. And again, I'm going to ask, did -- in reaching this conclusion, was that based on the document CX 1042?

A. Primarily, yes, um-hum.

Q. One second, I'll try to bring up that document on the screen.

Dr. Horovitz, the document itself is at tab CX 1042 in your binder, I believe it's the first document.

A. Um-hum, yes.

Q. And I've put it up on the screen here. Is that -- actually, it's not up here.

A. No, it's not.

Q. Here we go, I have it up on the screen.

A. That's the document, yes.

Q. And that's the document you're referring to?

A. Yes.

Q. And I've now put up on your screen a page from that document. Is this the page that contains the data you were referring to for your evaluation of the liver enzyme elevations?

A. I believe so. I have a number 00092. Is that --

Q. Yes, I believe that's right.

A. Yes, that's the same table.

Q. Now, could you explain what data you relied upon in forming your conclusions?

A. Well, primarily the -- this chart in the very right-hand column, which is 2 Successive -- and by "notable," that's defined in the protocol as elevations of liver function tests above three times the normal range.

Q. And that's the criteria you identified earlier?

A. Yes.

Q. What -- for the doses in this slide or in this document, what were the actual percentage of patients at that level for each of the doses?

A. Well, that's shown on the right, the very right column, zero percent for the immediate release product, niacin; zero percent for the 1000 milligram study; 4 percent -- yes -- for the 1500 and the 2000 milligram study -- group.

Q. Dr. Horovitz, and I apologize that I don't -- to make it easy I don't have it on the computer to bring up, but are there any other data in this package that are relevant to your consideration of the liver enzyme elevations with Niacor-SR?

A. Yes, I think the other important -- one of the other important aspects is to know if the patients who

did have elevated liver function tests had those reversed once they stopped medication, and indeed, that was the case. There is a table in this document that shows I believe 40-some patients who were then tested after the medication was stopped, and they all reversed back to normal.

Q. And is that the page that I've put up on the ELMO, SP 160093?

A. 93, correct, and I believe that's it, yes. It's hard to read, but I believe that's it.

Q. Now, what is the significance of the reversal of the liver enzyme elevations?

A. Well, it's very significant for the patient. It means that he does not have any hepatotoxicity and that his liver has given -- been given a chance to recover.

Q. And returning again to the previous page, I can actually bring that back, and you identified the 4 percent of patients at the 1500 and 2000 milligram dose of Niacor-SR who experienced the successive elevations of three times the upper limit of normal.

Is -- do you know how these elevations compare to those that you had testified that you saw in the McKenney study in the early 1990s?

A. Well, yes, the McKenney study had percentages

that were up above -- well above 50 percent, 60-70 percent.

Q. And how do the 4 percent elevations with Niacor-SR compare to the elevations seen with other cholesterol-lowering drugs?

A. It's in the ballpark. The statins -- there are, of course, a number of statins, and every one of them has had a percent of the patients in the studies having three times the upper limit of normal liver enzyme results. The percentage has varied depending on the study and the drug, anywhere from less than 1 to 4 or 5 percent.

Q. And aside from the statins, how does the 4 percent with Niacor-SR compare to other cholesterol-lowering drugs?

A. Well, the other significant one I think is the fibrates, which is another class. There's a drug called Tricor by Abbott Laboratories, benzofibrate, I believe, that for most of the study -- for all of the studies reports a number of approximately 5 percent for successive liver enzyme values over three times the upper limit of normal.

It also reports that if you only do single values, that 13 percent of the patients show values above three times the upper limit of normal.

Q. Now, you identified a moment ago the data that you relied upon to conclude that the elevations with Niacor-SR were reversible. Was that consistent with what was generally known about niacin itself?

A. I believe so. The literature -- the earlier literature is hazy, but most of what I've seen in the nineties, the studies indicated that if you take the patient off medication if he has high liver enzymes, off niacin, that it would reverse.

Q. And do you have an opinion one way or the other as to whether the reversibility of liver enzymes was known to be the case with other cholesterol-lowering drugs, non-niacin cholesterol-lowering drugs?

A. Oh, yes, that's -- that's well known and, in fact, the FDA certainly required that in the studies of pravastatin that we did, required that we show that.

Q. Dr. Horovitz, in reaching your opinions -- and you can put that document aside now.

In reaching your opinions regarding Niacor-SR, did you reach any conclusions as to what would be the ideal dose for marketing purposes?

A. Yes. If you look at the results of the study, you find that the 1500 and 2000 are relatively close in their efficacy, the 2000 a little more but not significantly more, and the side effect profile is

obviously better with the 1500 than the 2000. So, I would certainly have picked 1500 as the recommended dose level for this product. And I believe that Upsher-Smith probably came to that conclusion, because they were -- they had protocols for doing studies at the 1500 level.

Q. And what was the time frame of those protocols that you just referred to?

A. I believe the protocols were available at the same time the other two -- the results from the other two studies were, in the June time frame.

Q. They were available to whom?

A. To Schering to look at.

Q. I direct your attention to your binder, the SPX 71 and SPX 72.

A. Okay.

Q. I'd ask you, Dr. Horovitz, are these the protocols to which you were referring?

A. 71, correct, and 72, 1500, correct.

Q. Now, beginning with the SPX 71, could you describe the -- this protocol, what this type of study was?

A. Yes, it was a study to look at a combination of Niacor-SR with fluvastatin and also to look at 500, 1000 and 1500 once-a-day treatment.

Q. And now directing your attention to SPX 72, could you describe briefly what this study was designed to testify?

A. Yes. Once again, it looked at titration up to 1500 milligrams of Niacor-SR once a day at bedtime and compared it to a BID dose regimen.

Q. And let me pull it out, but a moment ago you referred to this study -- excuse me, this protocol in response to a question about the conclusion that the 1500 milligrams per day was the ideal dose.

Can you refer -- are you able to refer to -- in that document to what you were relying upon for that?

A. Yes, in the -- this protocol number -- well, I don't know that there is a number, but the --

Q. The page number at the bottom, it appears to be cut off on that one page, but judging by the one before it and the one after it, it's SPX 160015?

A. Well, first of all, it's SPX 72 we're talking about.

Q. Oh, SPX 72.

A. Yeah, and if you go to the first, second -- third page.

Q. SP 160015?

A. Okay, I don't have that on mine, but in the introduction to the protocol and the information to the

physician, there's a sentence that says, "The 1500 milligram per day dose seems to offer the best combination of efficacy and tolerance."

Q. And again, this was a document that you understand was provided to Schering in June of 1997?

A. Yes, I believe there is a date up top, 6/12/97, that it was received, I guess.

Q. Now, referring in this same document back to the second page in the entire document, Bates numbered SP 160014?

A. Yes.

Q. Under Study Procedures, I'm going to try to put it up on the screen here and see if I can --

A. 00114. It's 0011 --

Q. Oh, sorry, 0014, it should be the second page. I know it's difficult, I should have had the staples removed from these documents in the binder.

A. Let's see, yeah, mine says 00114.

Q. 114, I apologize.

A. Okay.

Q. And under where it says "Study Procedures," it says, "The dosing schedules are as follows," and it appears to have number 1, 2 and 3.

A. Yes.

Q. Can you explain what the significance of the 1,

2 and 3 is, what do those represent?

A. Well, they are different groups.

Q. So, they are different dosing schedules?

A. And different dosing schedules in each group, correct, but the primary part of the study for 18 weeks in two groups goes up to 1500 once a day, and the other group goes up to 500 in the morning and 1000 in the afternoon. So, it was 1500 broken up.

Q. Okay, that actually gets to my question. I see here it says that, "All patients will be titrated to 1500 milligrams a day using one of three dosing schedules."

A. Right.

Q. So, perhaps I didn't need to ask that last question.

The -- I just have a question about what the term "BID" and the term "QHS" mean.

A. BID is twice a day, in the morning and the p.m. in that case, and QHS I believe is once a day at bedtime.

Q. Okay, Dr. Horovitz. And, you know, before -- you don't have to open that back up, I had one other question.

Referring now -- I'm going to put it on the screen for you. It's that page that you had identified

before, "The 1500 milligram per day dose seems to offer the best combination of efficacy and tolerance."

A. Correct.

Q. I'm going to ask you -- it actually goes over onto the next page saying, "There may be some benefit in once a day bedtime dosing since this correlates with cholesterol production in the liver. The optimal dosing schedule of Niacor-SR has yet to be defined."

A. Right.

Q. And I'll ask you, what does that communicate to you in terms of the purpose of this study, if any?

A. Well, the purpose was to show, I think, that once a day would be good therapy, good efficacy and safety, and also to look at bedtime dosing, which a lot of people feel is the way you should give cholesterol-lowering agents, because the cholesterol turnover is much more active when you're sleeping at night. So, you want medication there.

Q. So, it would be comparing two things; it would be comparing the -- not only the once-a-day dosing but also the nighttime dosing?

A. Yes, and it would justify to the FDA that you could take it only once a day.

Q. This time I actually am done with that document.

JUDGE CHAPPELL: Does anyone else notice the Arctic air that's blowing in here? I've asked someone to check on it. We may be bundling up before the day is over. We go from sweltering heat to Arctic air.

THE WITNESS: I live in Florida, Your Honor, so I feel it.

JUDGE CHAPPELL: But you have been in Pittsburgh.

THE WITNESS: A long time ago.

BY MR. RAOFIELD:

Q. Now, Dr. Horovitz -- well, I don't need to bring that up anyway.

Having now reviewed the product profile for Niacor-SR and the efficacy profile and side effect profile, have you reached any conclusions about whether Niacor-SR met the product opportunity that you testified existed for an SR niacin in June of 1997?

A. Yes.

Q. And what did you conclude?

A. I concluded that the data supported that it was a safe and efficacious drug that certainly could be registered and sold if the selling was correct to justify the projections that were made.

MR. RAOFIELD: Your Honor, at this time I'm at a good breaking point. I, of course, can continue on,

but if we were going to take a morning break, I just wanted to offer this as a possible point.

JUDGE CHAPPELL: Yes, let's go ahead and take a break. It's 11:00. We will recess until 11:15. Everyone try to warm up.

(A brief recess was taken.)

JUDGE CHAPPELL: Back on the record.

They are adjusting the heat, so we should be thawing out slowly but surely. What will probably happen, it will be 110 in here, so we will have to turn it back.

You may proceed.

MR. RAOFIELD: Thank you, Your Honor.

BY MR. RAOFIELD:

Q. Dr. Horovitz, bringing back up the slide that you had for part two of your analysis and moving now to the next bullet point, "Strategic Value Niacor-SR Presented to Schering," could you explain what that's in reference to?

A. Yes. Any deal probably has some strategic value to the person or both parties doing the deal, and it's always important to look at strategic value, because it tells you what besides just numbers are important in doing that deal.

In this case, I believe I said before that in

the mid-nineties, the cholesterol market was just taking off, and all the major pharmaceutical companies were looking at it. If they weren't in this market, they wanted to be in this market. And specifically for Schering, it became important because they had a drug in their pipeline called ezetimibe, which was a novel kind of mechanism for lowering cholesterol, and they really didn't have much at that time in the mid-nineties in the field.

So, they had no corporate experience is the word I used. They really didn't know much about this field at that time, and it was -- it was important for them to try to get to learn, and one of the best ways to learn is to get a product to sell so that your company from the top down learns about this field, learns how to sell in this field.

And indeed, I think that was one of the reasons they looked at Kos' Niaspan before they started looking at Niacor.

Q. Do you recall when Schering was engaged in a valuation of Kos' Niaspan product?

A. I believe in the early part of '97.

Q. Now, Niacor and Niaspan are both sustained release niacin products, correct?

A. Correct.

Q. Have you seen any evidence that would lead you to conclude that Schering, as you say, had concluded that sustained release niacin could be used to -- for this strategic purpose?

A. Well, the evidence is that they obviously were interested in both products. First Niaspan was presented to them, and they looked at it, and then later Niacor. So, they obviously felt that a sustained release niacin was a product they'd want to look at.

Q. With respect to Niaspan, referring your attention to SPX 21 in your binder -- and what's the date of this document?

A. March 26th, 1997.

Q. And is this one of the documents that you reviewed in relation to Niaspan, Schering's evaluation of Niaspan?

A. Yes, I've seen it.

Q. Could you identify in this document what supports your conclusion that Schering viewed Niaspan as offering the strategic value you identified?

A. Well, a Mr. Russo from Schering is sending this to other people at Schering, and he makes a couple of points on the middle of the first page, number -- the second number 1, "Schering-Plough/Key would need guarantees on active participation and input into

promotional and strategic efforts for the brand." He's saying they want to participate in the marketing at least.

He then goes on to say, "This is essential to obtain the early strategic leverage and market expertise that would allow us to strategically bridge to our own 58235 compound," which was ezetimibe. And so he's saying there what I said, that he believed it was important for the company to be involved in this therapeutic area.

Q. And the language that you've identified, is that the language that I've just put up on the screen?

A. Yes, the -- you have highlighted part of that number 1, yes.

Q. Now, the date of this document was March 26th, 1997. Do you know when Schering began its evaluation of Niacor-SR in terms of was it before or after or during the same time period?

A. It was after.

Q. After this. And can you just explain how the language that you've identified in this document with respect to Niaspan supports your conclusion that Schering thought that a sustained release niacin product would offer some strategic value?

A. Yes, obviously they felt -- they knew that this

was a product for the hyperlipidemic area to lower cholesterol, and they would be selling to the same kinds of people. They would be learning about the therapeutic area, putting together promotional documents and things like that around this therapeutic area, and I'm sure felt that the potential of combination therapy later on with ezetimibe or the statins would be something that this would give them a chance to look at.

Q. Now, turning from Niaspan to Niacor-SR, have you seen any evidence that supports your conclusion that Schering thought that Niacor-SR could also offer this strategic value that you've identified?

A. Yes, I believe so.

Q. I'm going to direct your attention now to a document in your binder marked SPX 235. This is a document entitled Niacor-SR Supplemental Information with the date June 23, 1997, correct?

A. Correct.

Q. Now, Dr. Horovitz, do you know what date the Schering board of directors approved the Niacor-SR deal?

A. It was the latter part of June, I believe the 24th-25th.

Q. So, this document is dated before the Schering

board of directors approved the Niacor-SR deal?

A. If it was the 24th or 25th, yes.

Q. And is there any information in this document that supports your conclusion that Schering believed that Niacor-SR offered the strategic value that you identified?

A. Well, there's a note added to the last page I guess of the document or next to last, and it -- on the bottom of that page, 00003, it says, "Niacin SR will provide experience with the anti-cholesterol market and a complimentary product (along with the cholestyramine)," which also was one of the products in the Upsher-Smith deal, "when our ACAT cholesterol inhibitor in Research comes to market."

Now, I am assuming they're referring to ezetimibe, because early on ezetimibe was thought to be an ACAT inhibitor, and they probably didn't have another generic name at that time, but that's essentially saying that strategically, they wanted to get into this market to help them in the future market.

Q. And Dr. Horovitz, how did the strategic value that Schering identified in June of 1997 for Niacor-SR and cholestyramine relate to your opinions in this case?

A. Well, it related to my opinion that there was

value for Schering to doing this deal, and besides economic value, there was certainly strategic value to get them into this marketplace early on.

Q. And in your opinion in the pharmaceutical industry, is a strategic value a consideration when entering into a licensing transaction for a pharmaceutical product?

A. Absolutely, especially if a company feels that they have what we call in the industry a blockbuster or a large selling drug coming out of their research in the near future. They want to begin as early as possible to learn the market and hopefully to be able to sell other products in that marketplace.

Q. And the description that you just gave where you said a potential blockbuster, is that something that you would find applicable to this situation with Niacor-SR?

A. Well, I'm not sure you could classify Niacor-SR as a potential blockbuster, but I believe at that time Schering thought that in their research pipeline they had a potential blockbuster, and from what I know of that compound, where it is today, they probably still think so.

Q. And the strategic value that they identified with Niacor-SR related to the ezetimibe project?

A. I believe so, yes.

Q. Dr. Horovitz, the -- I've put back up on the screen the slide that you prepared for your part two analysis, and the final bullet point is -- relates to the evaluation of Schering's assessment of Niacor-SR and the assumptions to that assessment. Is that correct?

A. Yes.

Q. And I'd like to direct your attention to a document in your binder, SPX 2. Do you recognize this document?

A. Yes.

Q. And what is it?

A. It's a memo from a Mr. Lauda to a Mr. Kapur at Schering passing on a -- what he calls a commercial assessment for niacin that was prepared by Mr. Audibert.

Q. I'd like to direct your attention to the last page of that document, Bates numbered SP 1600047.

A. Yes, I have it.

Q. Dr. Horovitz, can you describe generally what this page represents?

A. Well, it's an attached table to the commercial assessment that lays out their -- the estimates for sales and market share and then has assumptions or

rationale for how I guess Mr. Audibert got those numbers.

Q. And are those the assumptions that you said that you identified to determine the reasonableness of the --

A. Right, to check on the validity of the number.

Q. Beginning with the first assumption, it says, "Dossiers --" and tell me if you don't see where I'm referring.

A. Yeah, I'm with you.

Q. It says -- let me try to zoom in a little bit more on that.

It says, "Dossiers approved late 1998."

A. Yes.

Q. What opinions, if any, did you reach as to the reasonableness of that assumption?

A. Well, considering that the pivotal trials were finished at the time that Mr. Audibert did this in June of '97 and considering that for the most part, in most ex-NAFTA countries, which was the territory Schering had, they would just have to take the integrated summaries from those trials and send them over to the regulatory bodies overseas, then that was probably a reasonable assumption if they got those out in the end of '97, that they could have approval certainly in some

countries in '98, the end of '98.

Q. And I can put it up on the screen if you'd like. I'm going to refer now to -- you just made a comment about depending on when they were going to get from Upsher-Smith the materials that they needed.

A. Right.

Q. I'm referring to CX 1042, which is the package you identified as containing slides about Niacor-SR that was provided to Schering.

A. Right.

Q. And I can put it up on the screen if you can see it there.

A. Um-hum.

Q. It's SP -- the page number is SP 1600079 for the record.

In your last answer, you said that the assumption that the dossiers would be approved in 1998 was reasonable if they were expecting to receive the materials they needed by the end of -- the latter part of 1997. Is that correct?

A. Yes.

Q. And does this slide provide any information that supports that assumption?

A. Well, this slide indicates that I guess Upsher-Smith was telling Schering in June of '97 that

they would have the final integrated safety and efficacy summary, ISS and ISE they're calling it, the final report in October of '97, which would give Schering the ability to transmit that report, anything else that they may want to add to it, to the regulatory bodies overseas and by the end of '97, yeah.

Q. Turning now to the assumptions, the next assumption says, "Reimbursed in most major markets."

A. Um-hum.

Q. What opinion did you reach, if any, as to the reasonableness of that assumption?

A. I felt that that was probably a valid assumption, especially when I looked at the pricing issue, which is three down, the product priced approximately 50 percent to atorvastatin. I think most of the overseas markets were looking for cheaper drugs for treating high lipids and would have agreed that a price at 50 percent of the statins would be reasonable and they would support reimbursement.

Q. And directing your attention to the third assumption, it reads, "Niacor-SR is the only SR niacin approved for hypercholesterolemia -- both as monotherapy and in combination with statin," and I'd like in this question to ask you specifically first with respect to the part of that assumption that is

that Niacor-SR would be approved for hypercholesterolemia, both as monotherapy and in combination with statin.

What opinions did you reach, if any, as to the reasonableness of that assumption?

A. Well, I believe that the pivotal trials, efficacy and safety supported it being approved for hypercholesterolemia as monotherapy. There were some combination studies with a statin anticipated and there was some data, but that may have taken the completion of that other protocol before they would get that labeling and approval. So, that may have come a little later.

However, my guess is that if this product got approved, many physicians would start using it in combination anyway. That was the practice in their hard-to-treat patients to get cholesterol levels down to where they want, they probably would have used a combination therapy.

Q. Now, the first part that I removed from that assumption, I believe it relates to the next bullet point, but you can bring us back to it if you'd like. The next bullet point is, "Similar products with similar labeling enter the market in late 2002."

My question is whether you reached any

conclusions as to the reasonableness of that assumption.

A. Yes, I think Mr. Audibert was probably anticipating that there would be SR niacin products eventually, because Schering would not have exclusivity, and that the best guess, his best guess of when they would enter the market would be late of '02, and I think he adjusted his -- can you go down a little bit?

Q. Yes.

A. -- his sales figures -- well, you can see it in market share, too. The market share would decrease some and the sales would decrease some as some competition started to come in.

Now, you know, that's -- I think he's being very conservative. A lot of times when you get competition, your sales -- your market share may go down a little bit, your sales may go up, because you find more interest in the drug, but he's being very conservative.

Q. Could you explain that last answer, how entry from a competitor can actually lead to increased sales in the market?

A. Well, it's a phenomena that happens, and the best explanation I have is that it's awareness, that

you now have two companies promoting similar products, and the physician gets more aware of the whole idea of an SR niacin, and -- in this case, and the experience shows that a lot of times when the second drug comes in, the market for the first one doesn't go down, it actually can go up.

Q. And I don't want to leave any loose ends, so I just want to go back and ask you if your answer to that one takes care of the part of the prior bullet that I left out, "Niacor-SR is the only SR niacin approved for hypercholesterolemia."

A. Well, yes, I guess I'm agreeing with his assumption that he would have exclusivity for a few years, but eventually, you know, there would be competition.

Q. And the next assumption is, "Product priced approximately 50% to --" actually, you know, before I go on to that next assumption, let me return to the assumption that competition would enter the market in late 2002.

You've testified that you're familiar with the product Niaspan?

A. Yes.

Q. And what was your understanding as of June '97 of the stage and development of that product?

A. It was filed, I believe, with the FDA and they were waiting for response for approval of their NDA.

Q. And are you familiar with Dr. Levy's opinion in this case that Niaspan's existence as a competitor at that point makes this assumption unreasonable?

A. Yes, I believe he commented on that.

Q. And do you agree with Dr. Levy's opinion on that point?

A. Well, there was -- there was documentation I saw in the discussions that Schering had with Kos that they certainly at that time weren't developing it in ex-U.S., and I know there was -- I believe it was Mr. Audibert's deposition where there were comments that he felt, because of his contacts with Kos, he being a former Key employee and a lot of the Kos people being former Key employees, that they didn't have any near-term interest in the overseas markets. They wanted to establish the product in the U.S. first.

So, yes, Kos could eventually have brought Niaspan SR as a competitor in the overseas markets, although I don't believe that's ever happened.

Q. The next assumption is, "Product priced approximately 50% to atorvastatin."

I believe you answered that one in connection with your answer on reimbursed in most major markets,

but if you need to add anything, I want to give you the chance to do that.

A. No, I'll just say again that I think the success of getting reimbursement for a niacin SR will depend on the pricing and the pricing significantly below the high-priced compounds, like the statins.

Q. The next bullet point is, "Side-effect profile of Niacor-SR doesn't significantly change."

Have you reached any opinion as to the reasonableness of that assumption?

A. Well, that's -- that's an assumption he's making to protect himself. Obviously if the side effect profile changes to the negative, then he can't stand behind those numbers, but based on the side effect profile from the data he saw in June and I saw that he saw in June, I would say that he has -- that they support his numbers.

Q. And the final bullet point listed here is, "Sales and market are worldwide (except the U.S., Canada, Mexico)."

A. Yes, he's just defining the rationale for his numbers as being in those markets that Schering has rights to under the agreement.

Q. Now, does this page indicate the percent market share that Mr. Audibert was projecting for Niacor-SR?

A. Yes, that's the second column going down.
Q. And what does it indicate?
A. He's projecting a market share starting at about 0.75 percent and going up to 1 and a half percent, which I felt was very small and reasonable for a Niaspan -- for a Niacor -- a niacin SR product.
Q. And is that last answer based on your review of the information with respect to Niacor-SR in this case?
A. Yes.
Q. This document is -- you've testified is the -- what you reviewed for the -- to evaluate the assumptions -- the reasonableness of the assumptions and the sales projections, correct?
A. This and everything else I reviewed went into that, yes.
Q. Did you reach any opinion as to the reasonableness of the document as a whole or as to the sales projections and the assumptions?
A. Yes, I concluded that his assumptions were reasonable and suitably conservative for evaluating the product.
Q. Dr. Horovitz, at the time that you were forming your opinions in part two of your analysis, did you consider performing a comparison of the level of due diligence that Schering performed in other deals to the

level of due diligence performed in Niacor-SR?

A. No.

Q. And you testified that you were retained in this case to -- in part to respond to Dr. Levy's expert report. Is that correct?

A. That's correct.

Q. Do you recall whether Dr. Levy's report addressed the issue of a comparison of the level of due diligence in other Schering deals to the level of due diligence with Niacor?

A. I believe he did mention that, yes.

Q. And I'm referring specifically now to the due diligence as opposed to the other part, which we'll address later, a comparison of other deals, in terms of the payments.

A. Yes, he mentioned that he thought the due diligence -- and I don't remember his exact words -- was small or something like that.

Q. And let me back up and clarify my question, if I could.

I'm referring not just to the level of due diligence performed with respect to Niacor-SR; I'm asking you whether you saw Dr. Levy in his report make reference to a comparison of that specifically to the level of due diligence performed in other Schering

deals.

A. I can't remember the exact words. I know he made comments on the due diligence, and he -- of course, he made other comparisons to other Schering deals.

Q. And what were those other comparisons, what subject did they relate to?

A. Mostly to noncontingent payments.

Q. Have you had a chance to review Dr. Levy's trial testimony in this case?

A. Yes.

Q. And do you recall whether Dr. Levy addressed -- and again, specific to due diligence and specific to a comparison of the due diligence in other Schering deals -- to the due diligence in Niacor-SR?

A. In his deposition or trial?

Q. In his trial testimony.

A. In his trial, yes, he did. He spent a lot of time on it.

Q. Have you now reviewed the materials relied upon by Dr. Levy in his testimony, his trial testimony?

A. No, not -- I haven't had time to look at everything he claims he looked at.

Q. Now, without having reviewed those materials, are you able to offer any opinion in response to Dr.

Levy's trial testimony on that point?

A. Well, I think that comparison is not -- and I'll try to be nice and say it's not useful. I don't see how you can compare due diligence from one deal to another. I mean, due diligence should be defined as doing the diligence that is due for that specific agreement, and it's going to vary depending on every deal. So, I don't know how you can relate time or boxes of material from one deal to the other. I think it's an exercise that does not tell you very much.

Q. You referred to considerations that varied from deal to deal. Could you give us an example of a few types of what considerations might influence the level of due diligence that you -- that a person evaluating a pharmaceutical product might perform?

A. Well, it depends on a number of things. First of all, how much information is available, the expertise of the person or persons doing the due diligence, the state of the product in development, whether it's a new chemical entity or an old drug. A new chemical entity is going to require much more diligence than a drug that's been around for 20-30 years and just is a simple reformulation. So, those are all factors that you have to take into consideration.

Q. If we could take the -- your reference to the information that was already available to the company, how might a company's preexisting familiarity with a product or a market relate to the level of due diligence that it would perform in evaluating a product?

A. Well, I think it certainly would help and make the process go a lot faster if the reviewer has a knowledge of the product and has background into the product. And in fact, in this case, Mr. Audibert I guess, in seeing a lot of the documentation that Kos provided, had a lot of background into this area of controlled release niacin. So, that would allow him to do a much faster review than if he was starting from scratch.

If it was a new chemical entity, he or anyone doing the due diligence would have to do a lot more reading and talking to experts and things like that, because there wasn't as much familiarity with a new chemical entity as there would be with an old drug.

Q. Okay, with respect to Mr. Audibert and the -- what you identified as the preexisting familiarity with the product or the market, have you seen any evidence that Mr. Audibert had information that would enable him to perform this type of evaluation as you've described?

A. Well, first of all, he -- his experience -- I mean, he has a biology background and his experience in the industry a lot of the time was with controlled release, sustained release products. In fact, he came from Key, which was one of the early developers of that technology.

And second of all, he certainly saw some of the documents I saw that Kos presented about the background of the market and the area. And -- oh, and third, he had -- my understanding is from what I read, he had been involved in the planning, the market planning, for ezetimibe and had spent most of the first part of '97 looking at the market and talking to country managers about the cholesterol market. So, he had a lot of that background, too.

Q. And how does that relate to your opinion?

A. Well, it says that he could get up to speed and do a diligence analysis much faster than probably most people could at that time.

Q. Now, another consideration you identified was whether a drug was a new chemical entity as opposed to a known drug.

A. Um-hum.

Q. And how would that relate to the level of due diligence that you might perform in evaluating a

pharmaceutical licensing opportunity?

A. Well, with a known drug, you have -- you have a lot of the clinical experience and experience in all areas, and you know what to expect, and if the data that you see on the old drug is what you expect, then you feel confident you can do a proper analysis.

In a new chemical entity, biology can surprise you. You never really know until you get detailed data, until you understand the mechanism, until you get extensive clinical or preclinical data, so it takes you a lot longer to do diligence, and you're never quite assured, as you would be with an older product.

Q. And how does that last answer relate to Niacor-SR and the evaluation of Niacor-SR?

A. Well, obviously Niacor-SR was a known pharmacological agent, niacin, with just a controlled release formulation, and as I said, it would be a lot easier and you would be more confident in looking at the data and analyzing it than you would with a new chemical entity.

Q. And the other -- I don't know if I picked up on all of them, but the other one that I think that you identified as consideration was the stage a drug is in development. How might that relate to the level of due diligence one would perform when evaluating a

pharmaceutical licensing opportunity?

A. Well, that's a mixture. I mean, if it's an earlier stage development, you don't have as much data from the clinic -- preclinical data to look at, maybe some earlier clinical, but you have to be much more cautious about those data, because just like I said before, it's an -- it's more of an unknown, and you have to think it through more. I would in early stage products probably look to experts much more than I would on a compound that I've known for years and is late stage.

Q. And what stage in development was Niacor-SR?

A. It was very late stage, had completed the pivotal studies in phase III and was near filing.

Q. And how does that relate to your discussion of the level of due diligence varying from deal to deal?

A. Well, I think in that case a knowledgeable person could do the due diligence reasonably quickly compared to other deals.

Q. With respect to all of these various considerations, how does that relate to what you testified was your disagreement with Dr. Levy's method of comparing the due diligence performed in some Schering deals as to the level of due diligence performed with Niacor-SR?

A. Well, I believe in his testimony, he used a couple criteria. One was the time that the deal took from start to finish, and the other was the weight of the documentation, and I don't think either of those are proper comparisons.

Q. Dr. Horovitz, during your career in the pharmaceutical industry, can you think of an example of a licensing evaluation which supports your conclusion that the level of due diligence varies from deal to deal?

A. Well, I guess every one, every one I've ever been involved in would indicate that there's variability, because there is variability. I mean, I can -- I can think of one that I did with a French company for two new agents, and we -- the up-front there was giving them drugs, and we looked at their drugs, they looked at ours. That negotiation went on for about nine-ten months. The final agreements were like six big volumes like those up there.

And then I can think of one that I did with a Japanese company that occurred like in a week without us getting a lot of information, because strategically, the company wanted to get into the antiviral area. This company in Japan had -- it was not a pharmaceutical company, but -- they were a fermentation

company, but they had discovered a very potent antiviral, at least in animal data, and we had other people who were, you know, trying to get that compound, and even though I wanted to see more studies in our labs of their product, they wanted to sign a deal, and the president of our pharmaceutical division said strategically, you know, we want that product, and do the deal.

JUDGE CHAPPELL: Sir?

THE WITNESS: I'm sorry?

JUDGE CHAPPELL: I need you to remove your hand from your mouth and speak up, especially at the end of your answers. The court reporter's having trouble hearing you.

BY MR. RAOFIELD:

Q. Dr. Horovitz, at the time that you were forming your opinion in part two of your analysis, did you perform a comparison -- and I'm changing the question slightly now -- did you perform a comparison of the amount and the type of the payments in other Schering deals to the type and the amount of payments in the Niacor-SR deal?

A. In my report?

Q. In forming your opinions at all.

A. No, not really.

Q. Do you recall whether Dr. Levy performed those types of comparisons in his expert report?

A. I believe so. There were a couple tables he developed in the back of his report and a couple paragraphs where he talked about other deals that Schering had done.

Q. Now, you testified that you were retained in part to respond to Dr. Levy's report, and you just testified now that you did not perform those types of comparisons. Can you explain?

A. Well, I believe in my report I indicated that, once again, I thought that those kinds of comparisons were not valuable, that they were apples and orange comparisons, and that you -- it's very difficult to find any deal that's the same for comparison, meaning it -- the drug is in the same stage, the therapeutic area might be the same, the interests of the parties are the same, because all those things go into a negotiation, and so you can't compare what was finally negotiated in one deal with another unless you have all those similarities, and I don't think I've ever seen a deal that's exactly the same as a second deal.

Q. Now, have you had the opportunity -- I think you said you have -- to review Dr. Levy's trial testimony in this case?

A. Correct.

Q. And do you recall whether he offered any opinions in his testimony here in trial which compared the amounts and types of payments that Schering made in other licensing deals to the amounts and types of payments with Niacor-SR?

A. I believe what I remember is he compared the Upsher-Smith deal with a number of other deals that Schering did just looking at what he defined as contingent -- noncontingent payments. I think that's correct.

Q. Now, have you gone back and reviewed the materials that Dr. Levy relied upon in his testimony?

A. No, I have not had the time to look at all those documents since his testimony.

Q. Do you recall any testimony of Dr. Levy -- well, let me back up.

Do you recall any testimony that Dr. Levy offered which related to his consideration or nonconsideration of the amount of research and development costs that Schering anticipated at the time of any of those other deals?

A. Yes.

Q. And what do you recall Dr. Levy's opinion was on that topic?

A. Well, Dr. Levy discounted any expenditure for internal R&D in the determination of what he called noncontingent payments, and I think that's completely wrong.

Q. Could you explain that?

A. Sure, there's a number of points. When you -- when you commit dollars in an agreement to doing R&D, that's a commitment for a budget, and that money can't be used for anything else. Now, it should be clear obviously that when you commit a certain amount of money for R&D and something happens, maybe that the drug dies, you may not spend that total amount, that's correct. But there's certainly -- when you start a study, when you start development of a drug, you commit dollars, and a lot of it is spent. Some of it even if the drug dies you would still spend, because you have to complete studies and report them to the FDA.

Secondly, I don't know if Dr. Levy understands that for most deals, the up-front payment is an R&D expense. It comes out of the R&D budget. Most companies I've ever dealt with, my own and at Bristol and Squibb and all the companies I've been working with since, if they're going to do a deal for a new product, the money -- the up-front money comes out of the hide of the R&D people, and the reason for that is that it's

an opportunity cost.

If they're going to spend money on this outside product to get it in, then they're going to do less internally in R&D, and -- except for maybe special circumstances where they could get it out of a different budget if it's a -- you know, a product that's already in the market, it usually comes from R&D.

So, you have to calculate that a good portion of any R&D commitment is going to be a noncontingent spending, and it's going to come from R&D.

Q. Dr. Horovitz, during your career in the pharmaceutical industry, were you ever involved with the in-licensing of a cholesterol-lowering drug?

A. Yes.

Q. And what drug was that?

A. That was a drug called pravastatin or the trade name of Pravachol, which Squibb licensed from a company in Japan called Sankyo in the mid-1980s.

Q. The mid-1980s.

A. And it was the second statin to be discovered.

Q. Could you just -- and I know it was 15 years ago -- but could you just describe the negotiations that took place in that deal?

A. Yes. We wanted the drug for sales and

marketing in the rest of the world except the Japan territory. Sankyo did not have the ability to sell it outside the Japan territories, so they were willing to discuss licensing it to Squibb.

Q. And did you during any portion of those negotiations visit their facilities in Japan?

A. Oh, yes, many times.

Q. And could you describe the negotiations that took place while you were there?

A. Well, I don't really remember anything much in detail except that we thought we had a deal on a Friday, shook hands, I went home. The business licensing person stayed, and on Monday morning, the National Institutes of Health released the results of a long-term study on the benefits of lowering cholesterol for treating heart disease, and Sankyo came back and said, wait a minute, this makes this drug even much more important, and we have to renegotiate the deal.

We had a quick meeting in Princeton with the president of the company and decided that actually they were right, and even though we tried to resist negotiating the deal, we had to, and we did renegotiate the deal.

Q. And did you go back and recalculate the values and do further work?

A. Actually, at the meeting, our decision was pretty clear. We were going to do it even without the calculations. We did the calculations later on, but -- and they supported that this was a deal we wanted and should go ahead with.

Q. And again, I understand that it was 15 years ago, but do you remember generally the terms in terms of the payments of the deal?

A. It's tough to go back. I may have mentioned something in my deposition that I thought it was around the $50 million range, but -- for up front. It may have been somewhat lower than that, I just can't remember. I can't even find anyone who's left at Squibb who would remember the actual details, but there was an up-front payment, and the deal was -- and this is an important fact -- the deal was primarily -- we would buy the material from Sankyo, they would produce it, and they would pay them -- they would guarantee us a margin, let's say 60 percent.

So, they would get 40 percent of the revenues, we would get 60. In that 40 percent obviously was their cost of goods plus a large royalty, but it was not -- not spoken of as a royalty but as a margin deal. And of course, most pharmaceutical companies would like a bigger margin than just 60 percent, but that's the

deal they structured.

Q. Now, do you recall -- at the time of the deal, do you recall what the anticipated research and development expenses Squibb anticipated?

A. Yes, we would have to do all the work essentially to develop this product to an NDA. They were in phase III in Japan, but most of the Japanese data would not help us with the FDA and most European regulatory bodies. I believe we anticipated in the range of $50 to $100 million to develop the drug. I think it really cost us more like $200 million, but it paid off, because this was a billion dollar drug.

Q. Do you recall in your review of Dr. Levy's trial testimony whether he discussed his consideration or nonconsideration of equity investments when making his comparison of the Niacor-SR deal to other Schering deals?

A. Yes.

Q. And what do you recall about his opinion?

A. Well, he felt that in general equity investments shouldn't be called noncontingent, and I believe his reasoning was that you could get a return. Occasionally companies do make equity investments, and then the company they invested in, the stock goes up, and they get a return on that money. In most cases,

that doesn't happen.

My former company just learned that. Bristol did a deal with ImClone for -- which I am sorry about, but I didn't do it -- Bristol did a deal with ImClone where they bought equity for a billion dollars, and six months later, they're writing off three-quarters of that. But it certainly is true that these investments could gain in the years.

Actually, though, the accountants and the CFOs at most companies, though, will not let you amortize very long. They like to write those investments off very quickly, sometimes the first year, sometimes two or three years, and I -- and they justify that because the experience has been that most of these deals, the equity investment does not pay back.

Q. Now, you mentioned the ImClone deal and I believe you mentioned that the equity investment in that deal was a billion dollars and roughly three-quarters of that was written off. Putting aside the equity investment involved in that deal, are you familiar with the up-front payment, the up-front cash payment involved in that deal?

A. Yes, the -- the noncontingent up-front payment was $200 million. There were other milestone payments after that, but the up-front noncontingent was $200

million.

Q. Dr. Levy, in reviewing -- Dr. Horovitz, excuse me, in reviewing Dr. Levy's report in this case, did you see that he offered an opinion about the efforts of the parties after the execution of the Niacor-SR license agreement?

A. In his expert report, yes.

Q. And what do you recall was his opinion?

A. He implied that after the execution of the agreement, there was little or no attempt to move the Niacor-SR ahead.

Q. I'm going to ask that you continue to try to speak up a little bit.

A. Sure, sorry.

Q. I know the microphone is a little bit far away.

And did you address or did you respond in your opinion in this case to Dr. Levy's opinion with respect to the efforts of the parties after the execution of the license agreement?

A. Yes, I believe so.

Q. Now, what was your general conclusion?

A. Well, I think there was documentation that Schering was making attempts to get their own people involved in learning about this product and to obtain all the information possible from Upsher-Smith, and

there were project meetings reports from Upsher-Smith indicating that they were moving ahead, at least for a while, on trying to get the information that Schering would need for their eventual filings.

Q. I'm going to direct your attention back, it's in your binder again, CX 1042, the package that you've talked about earlier, and I'll put it on the screen as I did before, SP 160079.

A. Right.

Q. At the time of the license agreement with Schering, which party was responsible for the regulatory filings to be made overseas?

A. That was Schering.

Q. And do you know at the time of the agreement what Schering's plan was in terms of when it would begin preparing the overseas regulatory filings?

A. It appeared from what I saw that their intention was to take the final reports, the integrated summaries which they were due to get in October, and then put them in order to be filed in the various countries that they had rights to overseas.

Q. So, the license agreement was in June of 1997, and they would obtain the documents from Upsher that they would turn into their overseas filing in October of 1997.

A. Correct.

Q. Now, have you seen any communications between the parties during the period of time after the license agreement?

A. Yes.

Q. And beginning first, bringing you back to the license agreement itself, how would you describe the -- that agreement?

A. Well, you mean the one signed in June --

Q. The one signed in June.

A. That was kind of what I would call a preliminary agreement. It set out the basic terms between the two parties and what their responsibilities was -- were, but it was not a final contract or a final document. And in fact, the preliminary document indicated that the two parties would complete what they called the detailed agreement.

Q. And when you say the parties anticipated a detailed agreement, is that something you've seen elsewhere or is that something you saw in the contract?

A. I believe that's in the original agreement that they signed.

Q. Now, do you recall when Schering's board of directors approved the Niacor-SR deal?

A. I believe it was June 24th or 5th of '97.

Q. Did you see any communications between the parties that related specifically to this detailed agreement?

A. After that time, yes. Shortly after -- I don't know the exact dates, but shortly after there was communication between Schering and Upsher-Smith on the agreement, a Mr. Thompson, I believe, from Schering and a Mr. Kralovec, and they were addressing the manufacturing part of the agreement, because Upsher-Smith was going to manufacture for Schering, and they were addressing other amendments to finalize the detailed agreement.

Q. And did you see subsequent communications in addition to the ones that followed immediately after the board approval -- board of directors approval?

A. Well, yes, I saw many. I saw Mr. Kapur trying to get more information from Mr. Troup and Upsher. Eventually I saw the -- Mr. Troup and Kapur putting the communication in the hands of Mr. Audibert and Mr. Halvorsen. And I saw Mr. Audibert sending what information he had to various people in R&D and manufacturing and different parts of Schering.

Q. Now, you referred in that answer to actions taken by Mr. Audibert after the June 1997 license agreement. What types of efforts did you see Mr.

Audibert engaging in during that time period?

A. Well, he was, as I say, passing on information to various people at Schering who probably would be involved in the overseas filing, and he was also trying to get meetings together with some of the overseas people, especially regulatory and also with manufacturing quality control people, trying to get them together with Upsher-Smith to go over information, and once again, to get them ready for overseas filings.

Q. And these communications you're referring to right now were in advance of October 1997?

A. Most of them, yes.

Q. Now, have you seen communications directly between Schering and Upsher, whether it was Mr. Audibert or not?

A. Oh, yes.

Q. And what did those communications relate to?

A. I believe I said that a majority of them, aside from the work going on on the agreement, were from Schering to Upsher trying to get the information they needed, the integrated summaries; from Upsher back indicating that there were some delays; and then from Schering back to Upsher saying, you know, when will we get them and can we have them at such and such a time.

Q. Now, you're referring to communications where

Upsher advised Schering that there had been some delays. Are schedule slippages or schedule delays something that are common in the pharmaceutical industry?

A. They're usually the prevalence, yes, they're more common than not.

Q. Now, were the communications that you saw and the actions that Mr. Audibert was taking internally at Schering consistent with what you would expect for -- with Schering's intention at the time of the license agreement to prepare the overseas filing when they got the materials in October of 1997?

A. Yes, from what I saw, they were taking the proper -- they were doing what they should be doing. Unfortunately, it was difficult, because they didn't have all the documents they needed at that time.

Q. Dr. Horovitz, I'm putting up on the screen another slide. Do you recognize this slide?

A. Yes, I believe this was something that Dr. Levy used in his testimony.

Q. And for the record, this document was identified during Dr. Levy's testimony as CX 1597.

Beginning there with Dr. Levy's first bullet point, "The non-contingent, unrestricted $60 million payment was grossly excessive," do you agree with Dr.

Levy's conclusion?

A. No, I do not.

Q. And why not?

A. Well, I believe I have testified that looking at both the actual economics that was projected for the deal and also the strategic reasons for considering the deal that the $60 million payment was not at all grossly excessive.

Q. And with Dr. Levy's second bullet point, "The due-diligence was strikingly superficial," do you agree with Dr. Levy's conclusion there?

A. Certainly not those words. The due diligence was done in a short period of time, but I don't see that it was superficial or strikingly superficial.

Q. And are those the -- for the reasons that you've identified earlier?

A. Correct.

Q. And do you agree that -- the third bullet point is, "Post-deal, neither party showed any serious interest in developing and marketing the drug," and do you agree with Dr. Levy's conclusion on that point?

A. No, I do not. I believe that the records show that both parties were communicating and trying to move ahead, although there were delays and eventually a decision not to go ahead, but in the post-deal period

of time of six months, there certainly was every effort apparently being made by both parties.

Q. And then finally, referring your attention to the top of the slide, Dr. Levy's ultimate conclusion that the $60 million was not for Niacor-SR, do you agree with Dr. Levy on that point?

A. I don't know how he comes with that judgment, because he couldn't put himself in the minds of the negotiators. I can't either, but everything I have seen says that the $60 million was for the deal that they made for Niacor-SR and was a reasonable amount to pay at that time.

MR. RAOFIELD: Your Honor, I have no further questions, subject to redirect.

MR. GIDLEY: Your Honor, I simply want to point out and let Mr. Eisenstat know, since I haven't spoken to him, I will have a small number of questions for this witness, and I do not mean to prejudice complaint counsel. I just want to call it to the Court's attention. I'm happy to ask my questions after the cross or now, whatever pleases the Court.

JUDGE CHAPPELL: Mr. Eisenstat, what's your preference?

MR. EISENSTAT: I'd just assume they get all their cards on the table, Your Honor. Let him ask the

questions, and then we'll know what the whole panoply is of issues, and then we'll do our cross.

JUDGE CHAPPELL: That would be standard procedure, so you go ahead, Mr. Gidley.

MR. GIDLEY: Thank you, Your Honor.

(Pause in the proceedings.)

MR. GIDLEY: Back on the record, Your Honor?

JUDGE CHAPPELL: Yes.

CROSS EXAMINATION

BY MR. GIDLEY:

Q. Dr. Horovitz, my name is Mark Gidley. I'm one of the attorneys for Upsher-Smith Laboratories, another one of the respondents in this matter. Good afternoon.

I want to return to the topic of SPX 2, which is a memorandum from Mr. Kapur -- to Mr. Kapur from Mr. Lauda, and I believe it's in your binder, and I'm going to put on the screen something you were testifying about earlier this morning.

Do you see that page, sir?

A. I do.

Q. What I've put on the ELMO is a page that's Bates numbered SP 1600047. It's entitled Table II, Niacor-SR Sales.

Do you see that, sir?

A. I do.

Q. And sir, this is a document you testified about earlier today. Is that correct?

A. Correct.

Q. And sir, I believe you testified earlier today that you had an opinion about the market shares in this document. Is that correct, sir?

A. Right.

Q. I'm sorry?

A. Yes, I'm sorry, yes.

Q. And I believe you testified that you thought that the market share from 0.75 percent to 1.5 percent was reasonable. Is that correct?

A. For this product, yes.

Q. And the product here, sir, is Niacor-SR. Is that correct?

A. Correct.

Q. And that's your opinion, sir?

A. That's right. In the markets that they had -- that Schering had rights to, which are defined at the bottom, the very last part of the document.

Q. And sir, just so our record is clear, could you just explain what you mean by your last answer?

A. Well, that Schering was only going to be selling in the markets outside the U.S., Canada and Mexico and that the market share that was calculated

for this drug was for those areas.

Q. Outside of the U.S., Canada and Mexico, correct?

A. That's correct.

Q. Sir, I want to direct your attention to another document, and this is a document from your binder, and I'll zoom in in just a second.

I'm showing you and what's on the screen is SPX 235. Are you there, sir?

A. Correct.

Q. And this is a document entitled Niacor-SR Supplementary Information, and at the bottom appears 23 June 1997. Do you see that, sir?

A. I see it.

Q. Directing your attention to B, Outlook for Total Market Growth, the first bullet reads, "Seventh best selling drug class today. Europe and Japan had 87 million hyper-lipemics in 1995, the majority were untreated."

Do you see that?

A. Yes, I do.

Q. Sir, do you have any opinion about the growth opportunity for Niacor-SR in Europe and Japan?

A. From that statement?

Q. Yes, sir.

A. Yes. As I believe I said in my testimony, I think in all parts of the world in the mid-nineties, the anti-cholesterol, anti-hyperlipidemic market was going to be rapidly growing.

Q. And sir, did your opinion that there would be rapid growth outside the United States include Japan?

A. Yes.

Q. And you just testified about growth. Do you see the second bullet, and there are a number of factors there?

A. Correct.

Q. Are any of those factors relevant to your opinion about growth in Europe and Japan?

A. They all are.

Q. And for the record, the first bullet says, "Aging Population," does it not, sir?

A. Correct.

Q. And why would that increase the market for a cholesterol drug?

A. Because as the population ages, you get more people who are going to show aberrant cholesterol metabolism. That is a function of aging.

JUDGE CHAPPELL: Hold on, Mr. Gidley.

Off the record.

(Pause in the proceedings.)

JUDGE CHAPPELL: You may proceed.

MR. GIDLEY: Thank you.

BY MR. GIDLEY:

Q. Dr. Horovitz, I want to change to a new topic.

Are you aware, sir, of the June 17, 1997 agreement between Upsher-Smith and Schering that's relevant to this case?

A. Yes.

Q. I don't believe it's in your exhibit binder, but it's well known to the attorneys here. I just want to make sure that you're on the same page as all the attorneys in this courtroom.

A. Okay.

Q. I'm showing you the first page of the agreement dated June 17, 1997.

A. I see it.

Q. It's on Schering Corporation letterhead -- thank you, Phil -- and as Mr. Eisenstat is pointing out to me, it bears the exhibit designation CX 348. Do you see that?

A. Yes.

Q. Turning inside the agreement, sir, I want to direct your attention to paragraph 7 of Exhibit A.

A. I see it.

Q. Let me see if I can zoom that in for you.

A. That's fine, I can read it.
Q. Are you able to make that out?
A. Yes.
Q. Now, sir, earlier today I understand -- I understood you to give an opinion about various valuation scenarios and about a $100 million payment in respect of Niacor-SR. Did I summarize your testimony correctly? Do you recall giving that -- do you recall giving that opinion?
A. I believe I said that certainly at $100 million, the value to Schering was reasonable, yes.
Q. And in giving that opinion, were you evaluating the license agreement between Upsher-Smith and Schering-Plough in respect of Niacor-SR?
A. Primarily -- actually, all Niacor-SR, even though I knew there were other products as part of that deal.
Q. Is your opinion about the $100 million payment contingent in any way on the supply agreement that appears in the last sentence of paragraph 7, which reads, "The SP Licensee shall have the option, in its sole discretion, of purchasing all or a portion of its supplies of Niacor-SR from Upsher-Smith at its cost of goods"?
A. I did not take that into consideration except

in reading it I said to myself that, well, this makes the deal even better --

Q. So, you think --

A. -- for Schering.

Q. I'm sorry, sir.

A. This would make the deal even better for Schering.

Q. So, you think that that ability of Schering to call upon Upsher-Smith to produce the product at Upsher's cost of goods would have positive value for Schering. Is that your opinion?

A. Yes, it would make Schering's margin better, and that would be positive.

Q. Sir, in your experience in doing pharmaceutical in-licensing transactions, have you ever had those transactions not turn out to be financially profitable for your company? Has it ever been the case that things have not turned out as you planned at the time of the deal?

A. If I wasn't under oath, I would try to avoid that question, but the answer is yes, I have.

Q. And like most human beings and most human endeavors, is it the case that the individuals are not clairvoyant, they do not see into the future with 100 percent accuracy? Is that correct, sir?

A. That's correct, and I think you have to remember that what you're dealing with is essentially biology, drugs. You can't predict completely what drugs will do, especially from small populations to large populations.

Q. Finally, sir, I want to talk about an opinion that was rendered earlier in this courtroom. In your experience in due diligence for in-licensing transactions, have you ever asked the other party to perform liver biopsies as part of the due diligence that you're performing on an in-licensing opportunity?

A. No, I don't -- I do remember that -- actually, in pravastatin, our friends at Sankyo suggested that we might have to do that, and that -- it's a little more common in Japan than it is in the United States, and we -- our response was, well, we didn't think that's something you want to do unless you really have overt hepatotoxicity, and we discussed the issue with the FDA, and they said don't be ridiculous, unless you, you know, really have hepatotoxicity, then we can discuss it. So, the answer is no, we've never -- I never remember any experience like that.

MR. GIDLEY: No further questions.

JUDGE CHAPPELL: Cross?

CROSS EXAMINATION

BY MR. EISENSTAT:

Q. Dr. Horovitz, you use a net present value calculation in your assessment of the value of the drug Niacor. Is that correct?

A. That's correct.

Q. And could you just explain what net present value means?

A. Well, it's the present value of the cash stream essentially that the company will receive for that deal.

Q. And --

A. Over -- usually it's done over a period of time. I used ten.

Q. And when you use the term "present value of the cash stream," is there a mathematical formula that tells us what the value of a payment in the future is today?

A. Yes, I used an Excel computer formulation. I don't know the exact -- I don't know that I could tell you exactly how that's calculated, but it's pretty standard in the industry.

Q. Now, let me show you a graphic that -- if I can get this going -- ah, yes, thank you.

Can you see that?

A. Yes, um-hum.

Q. My research told me that the net present value of a payment in one year was simply the payment amount divided by 1 plus r where r is the appropriate discount rate. Does that comport with your understanding of what net present value would be for a payment due in one year?

A. For a payment due in one year?

Q. Yes.

A. Yes, if you're just looking at the value of that payment without looking at the return.

Q. But that would be the value -- that would be the value of today's -- in today of that payment in one year. That's how I'd calculate it?

A. R is the discount rate, yeah, okay.

Q. And just for the record, that demonstrative was CX 1690.

And I have another demonstrative, CX 1691, and this is again my -- what my research told me was that the net present value of a payment due in two years would be the payment amount divided by 1 plus the appropriate discount rate squared, that is, one plus the discount rate times one plus the discount rate. Does that comport with your understanding of how you calculate the net present value?

A. You're multiplying the first year times the second year?

Q. One plus the discount rate is squared, and that amount is divided into the payment amount to bring it back to the net present value.

A. Without thinking that through, it sounds right.

Q. You're not comfortable with doing that?

A. No, I would have to think about that.

Q. Well, when we're calculating the net present value, if the payment amount changes, the net present value will change. Is that fair?

A. Correct.

Q. And when we're calculating the net present value, if the discount rate changes, that will also change the net present value. Is that fair?

A. I agree with that.

Q. Now, when Mr. Audibert was doing his analysis of the future stream of sales that Schering could get from Niacor-SR, he didn't know what the actual sales of Niacor-SR were going to be in any year, did he?

A. No, he did a projection.

Q. And that's because in 1997, no one could know what sales were actually going to be in the future.

A. I agree with that.

Q. And in fact, Mr. Audibert's estimates of the

sales for Niacor in each of those years was incorrect. Isn't that true?

A. In '97, he didn't know.

Q. But today we know that his estimates were wrong in every year, weren't they?

A. Today we know that there were never any sales.

Q. So, his estimates were wrong every year, correct?

A. You can -- you can say that, yes.

Q. The actual sales by Schering were zero in each of the years. Is that right?

A. That is a correct statement.

Q. And if we took the net present value of that stream of zero sales and the cost for Schering to enter into the deal, that net present value of that deal would be negative. Is that right?

A. That is correct.

Q. When Mr. Audibert did his analysis, Mr. Audibert and Mr. Lauda simply assumed that the product they were licensing was going to get European regulatory approval. Isn't that correct?

A. That is correct.

Q. And getting European regulatory approval is not certain at any time, is it?

A. No, it's never certain, that's correct.

Q. And it was not certain in 1997, was it?
A. It's never certain.
Q. And it wasn't back then when they did their analysis, was it?
A. If it's never certain, I assume it wasn't back then.
Q. And Niacor-SR never got regulatory approval in any European country, right?
A. It was never submitted, so it never got approval, that's correct.
Q. So, that assumption that they made, that they would get regulatory approval, that was another assumption that was simply incorrect.
A. Their assumption that they would get regulatory approval was based on what they knew in '97, the information they had and the fact that they anticipated filing it.
Q. And in retrospect, that assumption was incorrect.
A. In retrospect, it was never approved.
Q. Are there factors you could look at when you're doing an evaluation of a drug that would help you assess the likelihood that a drug would get approval?
A. Factors? Is that your question?
Q. Yeah, yeah.

A. You do that assessment based on your knowledge of what the regulatory bodies want and if your data will support what they want.

Q. So, would you look at the data to see if there were problems with the data to make an assessment of the likelihood of getting the regulatory approval?

A. Yes.

Q. Could patent licensing issues have an impact on the sales of a product in Europe?

A. Could patents -- I'm not sure what you mean by "patent license." Could patents, is that your question?

Q. Could patent issues affect the sales you would get from a product in Europe?

A. Well, they could affect your being able to sell obviously if -- if another party has a patent that restricts you, that covers your product.

Q. And could competitive issues, that is, could the competition you face in the market, could that affect sales you would expect to get in the -- for a product for sale in Europe in the future?

A. Yes, any analysis should look at the competition that you expect.

Q. Is one of the reasons that pharmaceutical companies do due diligence investigations is to find

out if there's any information available that would help them to get their hands around what the likely sales of this product were going to be in the future?

A. Yes.

Q. Now, in your work, I believe you assumed a discount rate of 10 percent. Is that correct?

A. That's correct.

Q. Does that 10 percent assume a certain probability that Schering would get European regulatory approvals for Niacor-SR?

A. Well, the discount assumes the possibility that either the drug would have some problems and be delayed or it may never have approval. That's why you take a discount.

Q. Can you translate that discount rate of 10 percent into the probability that Schering would make those sales in Europe that Mr. Audibert projected?

A. Yes, you can say that -- then you're calculating that there's 90 percent chance that it would meet those criteria that were in the analysis.

Q. So, your testimony is that if you apply a 10 percent discount, you're assuming there's only a 10 percent chance that Mr. Audibert will not meet those numbers?

A. There's a 10 percent chance that the

assumptions used for those numbers will change, yes.

Q. If one assumed that there was a -- only a 50 percent chance that the drug would get regulatory approval in Europe, what would be the appropriate discount rate to use to evaluate the drug?

A. Well, I never look at it that way. I mean, usually the discount rates are based on the knowledge that the company has as to the chance of getting on the marketplace for a drug, and it's usually related to where it is in the development process, because you -- it's very hard to put a probability number on something that you just don't know will happen or not happen.

Q. So, if someone assumed, though, that there was a 50 percent chance that Schering-Plough would be able to make these sales projections that Mr. Audibert put together, what would be the appropriate discount rate to use to find the net present value of that stream of income?

A. You could use 50. I mean, I -- if that's a clear assumption that you're making, that there's only a 50 percent, you could use a 50 percent. I think it would have been difficult to come up with that number at that time.

Q. And a 50 percent discount rate would have a substantially smaller net present value than using a 10

percent discount rate?

A. Correct.

Q. Could you tell us what a late stage drug is?

A. That isn't a clear definition, but in my definition, it is something that is -- that either has the results of the two pivotal trials for approval, clinical pivotal trials, or is well into the two pivotal trials so that the data would be available shortly.

Q. And when a company -- well, was Upsher-Smith -- was Niacor-SR in your view a late stage drug?

A. Yes.

Q. When a company has a drug that's a late stage drug and they're doing phase III clinical trials, these pivotal studies you've talked about, would that company have communications with the FDA?

A. I would assume so, yes.

Q. And do you know if in the industry a company would maintain a file of those communications with the FDA?

A. That is usually what is done, yes.

Q. Do you know if Upsher-Smith maintained a file of those communications with the FDA?

A. I -- I did see a few communications with the FDA. I believe one was put into evidence, a phone

communication, this morning.

Q. That's -- that was in your notebook?

A. Yes.

Q. And that's --

A. It was --

Q. -- SPX 267?

A. I'll check it. That's correct.

Q. Is it unusual for the FDA to communicate with companies by telephone like that?

A. No, not at all. There are much more telephone conversations than there are meetings.

Q. And is it typical for companies to maintain records of those phone conversations as Upsher-Smith did in this case?

A. When -- when there is something in the discussion that is relevant to what is necessary for the project and FDA's giving an opinion, yes.

Q. Do you know if anybody from Schering-Plough looked at the FDA files of Upsher-Smith before they licensed Niacor-SR?

A. No, I don't.

JUDGE CHAPPELL: Mr. Eisenstat, let me know when you finish this line of questioning.

MR. EISENSTAT: Your Honor, we could break at your convenience. Now would be fine.

JUDGE CHAPPELL: Okay, let's go ahead and take our lunch break. We'll recess until 1:45.

(Whereupon, at 12:45 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(1:45 p.m.)

JUDGE CHAPPELL: Mr. Eisenstat, you may proceed.

BY MR. EISENSTAT:

Q. Dr. Horovitz, before lunch we were talking about my little picture of net present value of a future payment, and you had told us how you had used a 10 percent discount rate to reflect the risk that the product wouldn't achieve its projected goals. Is that right?

A. Correct.

Q. Would it also be appropriate to include in the discount rate the cost of capital to Schering-Plough?

A. Yes, that essentially is usually included in that discount rate.

Q. And when you calculated the internal rate of return for your projections, would you then compare that to what Schering's cost of capital was to see if it was a good deal for them?

A. I didn't in the first go-through, because I didn't know, but I found out subsequently that they usually use 13 percent.

Q. So, one should compare that internal rate of return to 13 percent to see if it was a good deal for

Schering?

A. Yes, if that's what they're used to as their cost of capital.

Q. This morning you talked a little about dosing on different schedules during the day, and I have a question. Is dosing at bedtime the same thing as dosing with the evening meal?

A. No, it's actually not.

Q. Right before lunch we had started to talk about FDA files, and we had found that indeed you had gotten at least one document out of Upsher's FDA files.

Do you know if anybody from Schering ever inquired about the status of the FDA submissions to Upsher-Smith?

A. No, I don't know that.

Q. Is that something you probably would have done if you were in Schering's position, probably at least ask Upsher-Smith if there was any outstanding FDA issues?

A. Your latter statement I think I would have done, yes, I would have asked them if the FDA had any outstanding issues.

Q. In your experience, are you aware of any instances where a licensing deal was done for a late stage drug where there wasn't at least an inquiry made

of the licensor about the regulatory status of the drug?

A. Not in my experience, no.

Q. Do you know what a pharmacokinetic study is?

A. Yes.

Q. And what's a pharmacokinetic study?

A. Well, there are different studies. That term is all-inclusive of a number of different studies, but generically it's to look at the absorption, metabolism and excretion of a new chemical entity in the body.

Q. Do you have any experience with pharmacokinetic studies, doing them yourself for niacin?

A. For niacin myself, no.

Q. Have you had any experience reading them or reviewing them yourself for niacin?

A. No, I don't believe so.

Q. Would a successful pharmacokinetic study be necessary before Upsher-Smith could file their NDA with the FDA?

A. Before they could file?

Q. Yes.

A. Or get approval?

Q. Before they could file.

A. File? Not necessarily before they could file.

Q. Okay. Would it have been necessary before they

got approval?

A. My impression at that time was that the FDA in some cases had approved drugs without pharmacokinetic studies; however, it could affect the labeling of the product, meaning it would be difficult for them to get a sustained release labeling if they didn't show that it was sustained release with the pharmacokinetic study.

MR. EISENSTAT: One moment, Your Honor.

JUDGE CHAPPELL: Looks like a pretty thick box there, Counselor.

MR. EISENSTAT: Yes, yes. I still do things the old way, Your Honor, with paper. I'm not comfortable putting my precious documents in the computer yet.

JUDGE CHAPPELL: Well, as we've seen, the electronics do go out from time to time.

MR. EISENSTAT: May I approach the witness, Your Honor?

JUDGE CHAPPELL: Yes, you may.

BY MR. EISENSTAT:

Q. Dr. Horovitz, I'm going to hand you what's been marked as CX 1379, and it's a document that came from the files of Upsher-Smith, and I believe it has been admitted into evidence in this case.

Have you ever seen this document before?

A. I'm not sure at this point in time. It's possible, but I don't recollect it just looking at it this second.

Q. It appears to be a facsimile transmission from a Julie Reed at the Center for Drug Evaluation and Research at the FDA to Cindy Farner at Upsher-Smith Laboratories. Do you see that?

A. Yes.

Q. Would it be unusual when a company is working on getting a drug approved at the FDA for the FDA to send them faxes?

A. No, not at all.

Q. Would there be anything unusual about the fact that this came as a fax?

A. No.

Q. Could you turn to the second page of the document.

A. The second page or page 1 or 2?

Q. Yeah, it says page 1 at the top. The first page is that fax transmission.

A. Yes, I have it.

Q. And do you see that this communication is about Upsher-Smith's having a problem detecting niacin and niacin metabolites in plasma? On the first line under

Comments.

A. Yes.

Q. Could you tell me what metabolites are?

A. Metabolites are the breakdown of products in the body of the original drug you put in, in this case niacin.

Q. Okay. And is that something that the FDA would need to be able to measure in doing these pharmacokinetic studies?

A. Well, they would want to know if there are major metabolites, number one, and if there are, can they be measured and identified.

Q. And the first sentence says, "We have good reason to believe that your inability to detect niacin and niacin metabolites in plasma is due to inadequate study design of Protocol 901455."

A. Right.

Q. Do you know what Protocol 901455 is?

A. No, I don't know that I've ever seen it.

Q. As far as you know, that was never supplied to you?

A. I don't remember seeing it, not at least by that number.

Q. And under the numbered paragraph 3, the document goes on to say or the document reads, "The

following studies will need to be performed to support the Human Pharmacokinetics and Bioavailability section of a future NDA submission for this product.

"A, A single-dose, randomized crossover bioavailability/dosage form equivalence study comparing each dosage strength you intend to market with the currently-marketed immediate release form of niacin. The dose given should be sufficient to detect above baseline levels (1500-2000 mg)."

Do you see that?

A. Yes.

Q. Do you know if that's a standard kind of test that's run?

A. It's not an unreasonable request.

Q. The next paragraph says, "B, Single-dose, randomized crossover food-effect study comparing Nicolar under the following conditions: 1, fasting; 2, immediately after a high-fat breakfast; 3, immediately after a low-fat breakfast. The purpose of treatment 2 is to determine whether the dosage form will fail and dump niacin after this type of meal. Treatment 3 is the type of meal that a hypercholesterolemic patient might be expected to consume."

Again, have you seen requests for studies like this before?

A. Once again, I would not consider that an unreasonable request for this type of drug.

Q. And C is a "Multiple-dose, randomized crossover study using the dosing regimens used in the Phase III trials."

Again, is that the kind of --

A. Sometimes they do ask for multiple dose after single dose. I'm not sure with this drug that that would have been necessary, but it's not -- you know, it's not really an unusual request.

Q. And this is all about the Niacor-SR, right?

A. Yes.

Q. And D says, "As discussed in the 7/17/95 meeting, if the equipment, process, site, and formulation changes proposed by USL are carried out, a bioequivalence study between the formulations used in the clinical trials and the to-be-marketed formulations will be needed."

Again, is that typical, for them to ask for that?

A. Yes, when you change a formulation, they usually ask for what they call a bioequivalence study, meaning you're looking at the pharmacokinetic parameters of the formulation you had before compared to the new formulation, and you want to see that they

are equivalent.

Q. Had you seen this -- had you been in Schering's shoes and had seen this document before you signed the license for Niacor-SR -- and I believe the document's dated before the license was signed for Niacor-SR -- would this have raised any issues to you?

A. Not really, because these are all fairly easy and quick studies to do, assuming you're in the right dose range, as the FDA points out, and I don't think they would have cost much money or been very time-consuming to get done well before Schering would have had their filings overseas.

Q. Do you --

A. Assuming they were started.

Q. -- do you have any personal experience in doing any of these three types of studies?

A. Not myself, but I certainly have seen these done on drugs I was involved with and, you know, read the reports, et cetera, et cetera.

Q. Have you ever seen them done on niacin drugs?

A. No.

Q. Do you know how many PK studies Kos had to do before they finally got their NDA?

A. No.

Q. Do you know if these studies were done?

A. No, I don't know one way or the other.

Q. The next document I'd like to show you has been marked as CX 1382. Again, this is a document from the files of Upsher-Smith, and it has been admitted into evidence in this matter.

Just looking for a moment at the first page of the document, it appears -- I guess we have to look at the first two pages -- it appears to be a letter from Mark Halvorsen to Solomon Sobel. Do you see that?

A. Yes.

Q. Do you know who Solomon Sobel is?

A. Yes, he was a member of the Food and Drug Administration.

Q. Okay. Do you know who Mark Halvorsen was?

A. Yes, he was an employee of Upsher-Smith.

Q. If we turn back to the document, we come to a part labeled -- and I apologize, the heading's a little bad on this one -- it appears to read, "Upsher-Smith Laboratories, February 5th, 1997, Meeting Minutes with FDA Regarding Niacor-SR," and there's an IND number.

A. Um-hum, I think I have it. There's not -- it has a page 1 on the bottom?

Q. Yes.

A. Yes.

Q. It's on the ELMO right now.

A. Oh, I'm sorry.

Q. Is that the same page?

A. Yes.

Q. Okay. The first paragraph reads, "On February 5th, 1997, Upsher-Smith Laboratories, Inc. representatives met with FDA representatives from the Division of Pharmaceutical Evaluation II and the Division of Metabolism and Endocrine Drug Products to discuss pharmacokinetic issues regarding Niacor-SR."

Do you see that?

A. Yes.

Q. Is this -- is this something, again, that is typical in the -- or -- in the pharmacy industry, that after a meeting with the FDA, a company that met with them would send meeting minutes back to the FDA?

A. Yes, yes.

Q. And underneath that first paragraph, there's a list of participants in the meeting. Do you see that?

A. Correct.

Q. And one of the participants for the FDA is a gentleman by the name of Fossler?

A. Yes, I see that.

Q. And another one is Hunt. Do you see that?

A. Yes.

Q. Could you turn to the next page, then, the page

with the number 2 at the bottom, and the Bates numbering in the lower right-hand corner is 107434.

A. Correct.

Q. And I direct your attention to the second paragraph -- well, let me ask you this, I don't think I asked, have you seen this document before?

A. I believe it is coming back to me that I did see this, yes.

Q. This is one you saw?

A. One I saw.

Q. Okay. And the second paragraph says, "Dr. Fossler explained that the issue is qualifying the product for a sustained release or extended release claim. The efficacy and bioavailability conditions are probably met and the application is probably filable with existing data without an extended release claim. In order to obtain an extended release claim, metabolite levels need to be detectable showing the differences between an immediate release and the extended release dosage form. Mr. Hunt supported Dr. Fossler's explanation, indicating that Upsher-Smith does not have adequate data to meet the regulatory requirements for an extended release product."

Do you see that?

A. I see that.

Q. And that's consistent with your recollection that at least you'd need this kind of PK study in order to -- or a PK study in order to get an extended release claim?

A. That's correct.

Q. Was an extended release claim important for Niacor-SR?

A. I believe it would be, sure.

Q. Do you know whether Schering ever made any inquiry about this issue to Upsher-Smith?

A. I don't know one way or the other.

Q. Let's turn to the next page of the document, page 3, bearing the Bates number 107435.

A. Okay.

Q. And look at the first full paragraph on that page. "Dr. Fossler summarized that a crossover study between immediate release and sustained release products, evaluating for all the urinary metabolites, would be acceptable. Mr. Hunt commented that a lack of dose dumping would need to be demonstrated as well. Considerable discussion followed regarding whether the already performed single dose study, although inadequate in design, may adequately demonstrate a lack of dose dumping under fed and fasting conditions. It was noted that the product will be labeled to take with

meals."

Do you see that paragraph?

A. Yes.

Q. What does it mean for a product to be labeled to take with meals?

A. Essentially the label indicates that it should be prescribed to take while you're having a meal, eating.

Q. And that would be different than a bedtime dosing?

A. Somewhat different, yes. It depends on when you have your last meal.

Q. Are you being facetious?

A. No.

Q. No?

A. Some people eat very late.

Q. Okay.

A. When I was in college, my meal was 11:00 at night and then I went to bed, and that's why I have a stomach, but -- but normally, I would grant you that most people have a time between when they eat their last meal and when they go to sleep.

Q. Are you aware that when Mr. Audibert did his study, he reported that Niacor-SR was a product to be taken at bedtime?

A. I believe that was the plan, even though the two pivotal studies didn't necessarily study that. They were planning to study that, yes.

Q. So, at the time he wrote that study, that assumption was incorrect, right?

A. No. At the time he did his evaluation you're saying?

Q. Yes.

A. Their plan was hopefully to have it taken at bedtime. That's why they were going to do the subsequent studies, the two protocols.

Q. First of all, let me show you what's been marked as CX 1044.

A. Are we done with this or --

Q. Yes, for now, yes.

A. For now.

Q. In fact, you have this. I won't -- yeah, just -- do you have your notebook from this morning?

A. Yes.

Q. Could you look at tab 2, the tab that says SPX 2?

A. Okay.

Q. Do you have that in front of you?

A. I do.

Q. And could you turn to the page where the bottom

number is SP 1600044? The top heading says, "Niacor-SR."

A. All right.

Q. And the first line there says -- reads, "Niacor-SR is a patented sustained release niacin product designed to be administered at bedtime."

Do you see that?

A. Correct.

Q. Now, at the time he wrote this, it was not designed to be administered at bedtime, was it?

A. No, that's not correct. At the time he wrote this, there was no extensive clinical data to say it could be administered at bedtime, but there were protocols, if you want to call them, designs to study whether it could be given at bedtime.

Q. Okay, and you pointed out one of those protocols this morning. Is that right?

A. That's correct. They're in this book, too, I believe.

Q. Yes, is it SPX 72?

A. Yes.

Q. Now, at the time Mr. Audibert did his analysis, the study that's described in this protocol had not been done. Is that correct?

A. I believe that's correct.

Q. Do you know if this had started?
A. If this study started?
Q. If it had been started by the time Mr. Audibert --
A. Oh, I don't know.
Q. Do you know if it was ever started?
A. I don't know.
Q. And your testimony I believe is that this -- this synopsis or this protocol would call for a study of the Niacor-SR product in a bedtime dosing?
A. Yes, a comparison of a two-times-a-day group with groups that were dosed at bedtime.
Q. Could you turn to the page that -- of this document bearing the number SP 1600117? Do you have that in front of you?
A. Um-hum.
Q. It says, "3.2, Dosing Regimen."
A. Um-hum.
Q. And it says, "The mandatory seven-week titration period will involve dosing Niacor-SR for one week at 500 milligrams per day and six weeks at 1000 milligrams per day."
A. Um-hum.
Q. "The 18-week treatment will maintain the Niacor-SR dose at 1500 milligrams per day. Dosing will

be twice daily with meals or a single dose with the evening meal, depending on randomization. See Table 1 for summary."

A. Um-hum.

Q. Does that say anything about dosing at bedtime?

A. No, that's telling the physician to give the -- well, wait a minute.

That is the group -- that's group one, if you go back to the second page, that is 500 milligrams QAM and 1000 milligrams QPM. That's what they're talking about there. The other groups are QHS, which would mean at bedtime.

Q. What about the single dose with the evening meal?

A. Yes, that's in group one, the 1000 milligrams QPM.

Q. Do you see anything in the dosing regimen explaining the dose --

A. That's the twice -- excuse me, that's the twice daily dosing which is on page 0114 as group one.

Q. Do you see anything in that dosing regimen explaining the other dosing groups?

A. Not in that paragraph.

Q. Do you see it anywhere in that section?

A. I haven't looked, but it's clear in the study

procedure, at least it would be to me, that the other two groups are dosed once a day at bedtime.

Q. But could you look through the dosing regimen section and see if you see anything in there that it says about that?

A. You mean paragraph 3.2?

Q. Yes.

A. I'm just assuming that that 3.2 is only discussing group one, because they're the only ones that will be dosed twice a day.

Q. And you read that sentence, "Dosing will be twice daily with meals or a single dose with the evening meal," as being the group one people?

A. No, in group one, I'm reading that to say that they will be given dosing twice a day, once in the morning and once with the evening meal.

Q. I guess I'm just having a hard time understanding that. I just see that last sentence under 3.2, Dosing Regimen, "Dosing will be twice daily with meals or a single dose with the evening meal, depending upon randomization," and I didn't see anybody in group one who was getting --

A. A single dose.

Q. -- a single dose. Do you see anybody in group one who's getting a single dose?

A. No, that's correct. I think, then, that that probably is just a mistake. Either it's -- either it's a mistake in saying with the evening meal or it's a mistake on page 2 saying once at bedtime.

Q. Okay. And you don't know where the mistake -- which the mistake would be?

A. No.

Q. And you don't know if that study was ever undertaken?

A. I do not know.

Q. Going back to CX 1382, that's that February 5th, 1997 meeting minutes document, and that's not in your book.

A. Oh, that's the one you gave me, yes.

Q. Right.

A. This thick one.

Q. Yes. Could you turn to the page with the Bates number 107436, it's page 4 of the Niacor-SR February 5th, 1997 meeting minutes.

A. Yes, I have it. I have it.

Q. Do you see the last paragraph on that page, "Dr. Robbins asked if the NDA would be filable with the existing data and subsequently amending the application with the results of the new study. There was considerable discussion regarding this proposal. Dr.

Orloff concluded that under user fee regulations, the NDA should be approvable at the time of filing. Due to the known pharmacokinetic issues outstanding for Niacor-SR, the FDA should not file the NDA without the requested pharmacokinetic study results."

Do you see that?

A. Yes, I do.

Q. Does that indicate to you that they would have -- Upsher-Smith would have needed to complete their pharmacokinetic study before they could file their NDA?

A. That certainly is what it sounds like.

Q. Do you know if they ever did their pharmacokinetic study?

A. No, although I know at the time -- in the summer period of time, I did see Upsher-Smith project team minutes, and they were certainly working on it. They had an outside contractor working on the assays, and it certainly indicated to me they were planning on doing it. Whether they ever accomplished it, I don't know.

Q. Did you ever see any communications between Upsher-Smith and Schering where Upsher-Smith told Schering that they had to do this pharmacokinetic study?

A. No, not specifically. I never saw that.

Q. Did you ever see any indication from Upsher-Smith asking for help from Schering on doing a pharmacokinetic study?

A. No, I can't remember that I saw anything.

Q. Turning to the next page of the document, page 5 of the Niacor-SR February 5th, 1997 meeting minutes, which bears the Bates number 107437, the paragraph reads, "In summary, Upsher-Smith and the FDA agreed to the following conclusions: A three-way crossover study will be performed with one 1000 milligram immediate release niacin fasting arm and two 1000 milligram sustained release arms, one fed and one fasted. There will be approximately 10 to 15 subjects per arm, with urine collection at predose, 0 to 1, 1 to 2, 2 to 4, 4 to 6, 6 to 8, 8 to 12, and 12 to 24 hours post-dose. Urinary excretion of niacin and its metabolites will be analyzed. Standardized meals will be administered throughout the study. No aspirin will be used due to its effects on the metabolism of niacin. Upsher-Smith dissolution data to be provided will be evaluated to determine if a 250 milligram arm, either fed or fasted, is necessary."

Does that summarize to you what Upsher-Smith now had to do with respect to pharmacokinetic studies?

A. Well, that's read exactly from what the FDA apparently concluded.

Q. All right. You said you thought pharmacokinetic studies didn't take very long and didn't cost very much. Is that right?

A. That's correct.

Q. Do you know --

A. Comparatively.

Q. Excuse me?

A. Comparatively to phase III clinical trials.

Q. Do you know of any reason why Upsher-Smith wouldn't do their pharmacokinetic study if they were serious about moving forward on Niacor-SR?

A. No.

Q. The next document I'd like to show you has been marked CX 1383. It is also from the files of Upsher-Smith, and it has also been admitted into evidence.

This appears to be another fax from the Center for Drug Evaluation and Research of the FDA to Cindy Farner at Upsher-Smith. Do you see that?

A. Yes.

Q. Could you turn to the second page of the document.

A. Um-hum.

Q. And this is a document -- on the front it's dated March 26th, 1997, and remember the last paragraph that we read in the last document, they were talking about getting dissolution data and seeing if they needed to add another arm to their study?

A. Correct.

Q. And do you see in the first paragraph here, we have an answer to that question, and the paragraph says, "Upon review of the comparative dissolution data, it appears that the 250 and 500 milligram differ sufficiently such that a waiver of the requirement for pharmacokinetic data for the 250 milligram tablet cannot be granted. Therefore, the proposed study design should be amended to include a fourth treatment arm administering a 4 X 250 milligram tablets under fed conditions."

Do you see that?

A. I do.

Q. And so that was a continuation of that discussion they had at their previous meeting?

A. I believe that to be so.

Q. And then paragraph 2 says, "We continue to believe that the recommendations as faxed to Upsher-Smith on 1/13/97 represent the ideal manner in which to study the controlled release characteristics

of Niacor-SR. However, as discussed in the 2/5/97 meeting between your firm and the Agency, if Upsher-Smith feels that single doses of niacin above 1000 milligrams represent a significant safety concern when given to normal volunteers, then the design as outlined in your submission dated 2/24/97 will be sufficient for filing, provided that a 250 milligram treatment arm is added to the study. It is emphasized that approval of Niacor-SR as a controlled-release product is dependent on the results of the submitted study, and not merely on its completion."

Do you see that paragraph?

A. I do.

Q. If you were in the shoes of Schering-Plough and were going to license Niacor-SR from Upsher-Smith, would you have wanted to review this correspondence before you signed the license deal?

A. Well, if I knew about it, I would like to have seen it, yes.

Q. The last document I want to show you about these PK studies is a document bearing the number CX 1111, also a document from the files of Upsher-Smith and also admitted into evidence.

This is a letter from Paul Kralovec, chief financial officer, Upsher-Smith, to Mr. Ray Kapur.

Have you seen this document before?

A. I believe so, yes.

Q. Do you see the first paragraph where it says, "Per your request to Ian Troup last week, I am writing to confirm that Upsher-Smith Laboratories, Inc. has suspended all research on Niacor-SR. There were multiple reasons for this decision. First and foremost, an additional multiple-dose pharmacokinetic study was required prior to submitting an NDA. In light of Niaspan's FDA approval, Upsher-Smith's NDA would have been two to three years behind the launch of Niaspan."

Do you see that?

A. I see the paragraph, yes.

Q. Is this -- do you know if this is the same pharmacokinetic study that we were talking about back in the spring of 1997?

A. No, I do not.

Q. Do you know if they had done any work, actual work, on getting the pharmacokinetic studies done for this drug?

A. Well, I never saw any reference to the study being underway or finished. I did see reference to planning the study.

Q. And that was in the Upsher-Smith documents you

said?

A. Yes.

Q. Do you know why Upsher-Smith waited until October 6th, 1998 to tell Schering-Plough that an additional multiple dose pharmacokinetic study was required prior to submitting an NDA?

A. I don't know that they did. I don't know why.

Q. You haven't seen any references to Upsher-Smith communicating to Schering prior to this date about the pharmacokinetic study, have you?

A. Not that I can remember.

Q. Sitting here today, can you think of any reason why Upsher-Smith wouldn't have completed its pharmacokinetic studies if they were interested in moving forward on Niacor-SR?

A. No, I believe they certainly could have if they would have started them or at least for a period of time. They are not long-term studies.

Q. Is intellectual property an area where a pharmaceutical company will make inquiries before licensing a late stage brand name drug?

A. Certainly a pharmaceutical company would want to analyze what an intellectual property situation is.

Q. In your experience, have you ever been involved in an in-licensing deal for a brand name -- late stage

brand name pharmaceutical where there was no review of the intellectual property issues?

A. Well, as I just answered the previous question, there's always a review. That review may be just to say is there or is there not a patent. If there's no patent position, the review doesn't take very long. It takes five minutes. If there is a patent position, then, of course, you would want to know how complex, are there any problems with that patent position, things like that. Then your review is going to be more extensive and at one point in time maybe involve a patent attorney.

Q. Do you know if Upsher-Smith did have a patent position for its Niacor-SR product?

A. Well, they -- they had a patent on their formulation with niacin; however, that patent could have easily been gotten around by people with other technology for SR, and I believe that Mr. Audibert just assumed that they would not have any exclusivity for that product, and that's how he did his analysis.

Q. Do you know if anyone from Schering made any further inquiry besides Mr. Audibert's assumption regarding the status of the intellectual property of Upsher-Smith as it related to Niacor-SR?

A. No, I do not. I believe that some of the

material that Schering got from Upsher-Smith in the beginning indicated that there was a patent, but I don't know if there were any further inquiries.

MR. EISENSTAT: At this point, Your Honor, I'm going to be discussing an in camera document.

JUDGE CHAPPELL: Okay, at this time I'll have to ask the public to leave the courtroom. We are going into in camera session. You will be notified when you're free to enter the courtroom again. Thank you.

(The in camera testimony continued in Volume 16, Part 2, Pages 3877 through 3881, then resumed as follows.)

BY MR. EISENSTAT:

Q. Dr. Horovitz, are you familiar with the term "indications" with respect to a drug?

A. Yes.

Q. What are drug indications or what are a drug's indications?

A. Indications describe what the drug can be prescribed for, essentially what the Food and Drug Administration allows in the labeling for the physician to use the drug for.

Q. So, the indications actually appear on what they call the labeling of the drug?

A. That's correct.

Q. Is the labeling the same thing as package inserts?

A. The labeling is -- yes, the package insert describes the labeling.

Q. Okay. And is the labeling for a drug submitted to the FDA for approval?

A. That's correct.

Q. And sometime during the development of a late stage drug, will the company developing the drug typically write up draft labeling?

A. Yes.

Q. And in performing due diligence for in-licensing of a pharmaceutical product, is looking at the draft package inserts or labeling relevant?

A. If it's available. It depends on, you know, the stage of the product and if a draft package insert has been developed.

Q. And would you -- when you were doing in-licensing, would you always ask if a draft labeling had been done?

A. For latter stage products I believe.

Q. And the labeling would be important for in-licensing a drug because you would look at it to tell you what your salesmen could say about the drug. Is that right?

A. Yes, that's correct. I mean, you can -- you can -- you can guesstimate what the labeling will be based on the data from the pivotal trials. The actual draft labeling just puts that information in a form that would be similar to a package insert.

Q. Do you know if anyone from Schering reviewed Upsher-Smith's draft labeling for the Niacor-SR product?

A. I do not know.

Q. Do you know if anyone from Schering even inquired to see if there was draft labeling for the Niacor-SR product?

A. No, I don't know.

Q. But that's something you would have done if you had been in Schering's shoes, make the inquiry?

A. I would have asked if they had a draft label.

Q. And if they had it, you would have reviewed it?

A. Yes.

Q. Now, by June of 1997, Kos had submitted its NDA to the FDA. Is that right?

A. I believe that's correct, yes.

Q. And when Schering was reviewing the Kos product, Niaspan, Schering got a copy of that draft labeling, didn't they?

A. I -- I don't know. Schering got some documents

describing the product, but whether the draft labeling was included, I don't know.

Q. I'd like to show you what's been marked as CX 540, and this is a document this time from Schering-Plough's files.

A. Um-hum.

Q. The first page is a memo from Karin Gast to Rudy Ress, copying a number of other people, dated February 11th, 1997. Do you recall if you have ever seen this document before?

A. I believe I have.

Q. And there are a number of attachments to the -- to this one-page memo that are listed there on the front, and the second attachment reads on the front page, "Proposed labeling, excluding the indications section."

Do you see that?

A. Yes.

Q. And the second -- the next point says, "A single page entitled Preliminary Labeling Indications, which they believe are likely to be approved."

Do you see that?

A. Yes.

Q. Is this the kind of information you were talking about when you said you'd look for draft

labeling and then review it if you could get it?

A. Well, certainly this product at this time was very close to filing if it hadn't been filed already, and -- and may have been by that time, and one would expect if you file a product that you have proposed labeling. That's part of the package.

Q. And this is what you would expect to see from a company like Kos?

A. From a product that was at this stage, yes. You would have to have the draft labeling, because you had the NDA.

Q. And I direct -- well, let's stick with that first page just for a minute more.

Do you see the bottom line of typed text on the page, "Please distribute this material to the CV Licensing group for review and discussion at the next meeting (3/3/97)"?

Do you see that line?

A. Yes, I do.

Q. Do you know if Mr. Audibert was a member of the CV licensing group?

A. I don't know.

Q. And let's turn to the page that bears the number SP 002804. It's headed at the top Preliminary Labeling Indications for Niaspan.

A. I have it.
Q. Do you have that page in front of you?
A. Yes.
Q. Do you see the fourth preliminary indication, "Reduction of recurrent myocardial infarction (MI) in patients with a history of MI"?
A. Yes.
Q. Do you know what myocardial infarction means?
A. Yes.
Q. And what is myocardial infarction?
A. Well, people use that for describing heart attack. It's a -- an infarct is a damage to the heart muscle, the myocardial.
Q. And do you know what it means for it to say, "Reduction of recurrent myocardial infarction in patients with a history of myocardial infarction"?
A. Yes, I believe in my initial testimony I indicated that niacin had been shown to be successful in preventing subsequent, I called it, recurrent myocardial infarcts, and a number of large studies had been done of niacin and other drugs and placebo to indicate if you took niacin, you would have less chance of having a subsequent infarct.
Q. And Kos was able to rely on those studies to seek to get this preliminary --

A. Yes, I believe that their labeling now includes that phrase -- it's really given by the FDA as an indication for niacin and is part of what we call class labeling. Any niacin product that gets approved would have that labeling.

Q. And do you see the fifth preliminary labeling indication, "Slowing progressive --" and I don't know how to pronounce that word --

A. Arteriosclerotic.

Q. " -- arteriosclerotic disease in patients with a history of coronary artery disease when used in combination with bile binding resins."

Is this another one of those things you called a class label?

A. I believe that would have been a class labeling, yes.

Q. And what is arteriosclerotic disease?

A. It's the plaque build-up, what people know as plaque, the build-up of lipids and other factors in the arteries to prevent blood flow.

Q. And do you know whether by June 1997 Upsher had done any draft labeling for Niacor-SR?

A. No, I don't know. I did eventually see a draft label, but I can't remember the timing.

Q. And let me show you what has been marked

CX 976, again a document from the files of Upsher-Smith that's been admitted into evidence.

The first page of this is an interoffice memorandum from Lori Freeze to Phil Dritsas and Mike Kirshen. Do you see that?

A. Yes.

Q. With carbon copies to Denise Dolan and Jim Maahs. Do you see that?

A. Yes.

Q. The first sentence says, "I have attached a copy of the most recent draft of the Niacor-SR package insert."

Do you see that?

A. Yes.

Q. And that would be the draft of the labeling?

A. Yes.

Q. And the third paragraph on the page says, "Please review the information in this draft package insert and give me your comments so we can incorporate them into the final insert."

Do you see that?

A. Yes, I do.

Q. Have you ever seen this before?

A. I don't know if I saw this cover memo, but I believe I did see a package insert draft of Niacor-SR.

Whether it was this draft or a subsequent one, I'm not sure unless I get to study it for a while.

Q. Do you know if there was a subsequent one to this one before the Schering license deal was entered into?

A. A?

Q. A subsequent draft package insert.

A. After this one?

Q. After this one, before the --

A. I would doubt it, because this is about the same time.

Q. Well, this is June of '96.

A. Oh, '96, I'm sorry. Before June of '97?

Q. I didn't see one, but I didn't know if you --

A. I -- I remember seeing one, and I remember it as a kind of different format, but whether it changed -- most companies will update this as they get more information. So, when they -- when Upsher-Smith did their update, I just don't know.

Q. Could you turn to the page bearing the number 1003785, and I apologize, the numbers are very small.

A. Yeah, I can see it. Okay, it starts, "Indications and Usage"?

Q. "Indications and Usage," yes. Can you look through that section and see if you see any indication

for the reduction of recurrent myocardial infarction or the slowing of progressive arterio --

A. Arteriosclerotic.

Q. -- arteriosclerotic disease?

A. I don't see it on this page.

Q. And do you see it on the subsequent page? I think it continues on the next page.

A. No, I do not. They seem to be focusing at this point anyway just on cholesterol.

Q. Would a -- do you know whether a sustained release niacin product that had an indication for reduction of recurrent myocardial infarction in patients with a history of myocardial infarction, whether a sustained release niacin product with that indication would have a competitive advantage in the marketplace over a sustained release niacin product that did not have such an indication?

A. Well, that's a hypothetical question, because --

Q. Yes.

A. -- I don't think that will ever happen, but if it did, if for some reason there wasn't class labeling anymore, then it might have an advantage.

Q. That is, that the drug that had that indication --

A. Had the indication, right.
Q. Would the same thing be true for the arterio --
A. Arteriosclerotic plaque?
Q. Yes.
A. Yes, if that ever happened.
Q. Do you know whether, in fact, Upsher-Smith qualified to get that class labeling?
A. If they would have filed their NDA, I believe they would have got that class labeling, yeah.
Q. Did you read the deposition of Mark Halvorsen taken in this proceeding?
A. I believe so, yes.
Q. Let me show you what's been marked as CX 1688, which is two pages taken from that deposition. Let's start on the page -- page number 168. Do you see the question and answer at the top:
"QUESTION: Do you know why it was decided to stop work on the NDA for Niacor-SR?
"ANSWER: Personally I don't know what the overall reason was for Upsher-Smith as a whole. There were multiple discussions regarding advantages and disadvantages."
Do you see that section?
A. I see it, um-hum.
Q. Let's turn to the next page then, the page that

starts with the examination by Ms. Bokat.

"QUESTION: What were the disadvantages?

"ANSWER: One is that we could not match the -- all of the package insert indications that Kos had for their product.

"QUESTION: What package insert indications could Upsher-Smith not match?

"ANSWER: I group them in three categories. One is the lipid parameters. As I stated earlier, I believe we were equivalent to Kos' lipid parameters.

"The second indication they have is a reduction in myocardial infarctions. The third is for halting progression or actual regression of arthrosclerosis. It's the second and third that Upsher-Smith did not collect information in their Niacor-SR protocols to be able to get those indications."

Do you see that?

A. Yes, I do.

Q. Does that indicate that had Niacor-SR reached the marketplace, it would have been at a competitive disadvantage to Kos, who was able to have those two?

A. No, I think it indicates some naivete of Mr. Halvorsen in the RX area of drugs. He was primarily used to over-the-counter drugs at Upsher-Smith, and that if Kos got these indications, which they did, they

got them without doing any of their own studies in this area. They got them from literature, and there was no reason why Niacor wouldn't get the same --

Q. Even if they didn't collect the information to get those same indications?

A. Even if they didn't collect the information, I said I would be very surprised -- in fact, I would be amazed if Kos collected this information. All you have to do is cite to the references and you get the class labeling.

(Pause in the proceedings.)

BY MR. EISENSTAT:

Q. I'd like to hand you what's been marked as CX 574, and this is a letter from Cecil C. Schmidt to -- of the law firm of Merchant & Gould to Peter Mansa of Jenkins & Gilchrest dated August 19th, '97, and handwritten on the first page is "CC: Ian Troup, Vicki O'Neill."

A. Yes.

Q. Have you ever seen this document before?

A. I'm not 100 percent sure, but I think I may have seen it.

Q. Do you know what the document is in reference to?

A. I believe it's referring to an analysis on

patent --

Q. It's about the patent cross-license agreement?

A. It -- I believe so, yes. I'm not sure who the principals of the memo are or who's writing who, but -- but yes, I believe that's the case.

Q. For the sake of this question, let me ask you just to assume that Cecil Schmidt is representing Upsher-Smith and Peter Mansa is representing Kos Pharmaceuticals.

A. Okay.

Q. Do you see the paragraph that says, "As you know from our discussions, I've advised my client as follows: One, with regard to co-marketing and similar relationships, they are free to manufacture and sell a multiple dose niacin product and they are free to sell a once-a-day niacin product which is not indicated for use in the evening or at night."

Do you see that?

A. Yes, I do.

Q. And it says, "They are free to market worldwide a once-a-day, at-night product so long as this is not through a co-marketing arrangement, i.e., it is on their own."

Do you know if that would apply to the license agreement that Upsher-Smith signed with Schering?

A. No, because I don't know if this refers to U.S. or what countries it refers to. Obviously the analysis should be done for the territories that Schering was licensed for, and this letter doesn't tell me that.

Q. Well, under 2, it does say they're free to market worldwide a once-a-day, at-night product, so long as it is not through co-marketing arrangements, i.e., it is on their own.

Do you see that?

A. Yes, but that doesn't say that they can't sublicense in other countries for that usage. I mean, this letter doesn't indicate whether his analysis was U.S., Europe, Japan or anywhere.

Q. If this letter covered Europe, would that affect the Upsher-Smith/Schering deal?

A. It would -- it could possibly affect them with their labeling, the at night, yes.

Q. If this did affect the European deal, would it preclude Schering from making a once-a-day, at-night claim?

A. If they had patents in the countries that Schering would market that covered a niacin SR to be used at night, then that probably would be precluded. Those are very tough patents to get in overseas countries, and I seriously doubt whether they got them,

but it's possible.

Q. Sure. Could you turn to the next page of the document?

A. The last page?

Q. The last page, and the top paragraph says, "Based upon my discussions with my client, it is my present belief that they are unlikely to proceed with any of the current co-marketing opportunities, but rather, will proceed in due course with their own once-a-day, at-night product."

Do you know what that refers to?

A. No.

Q. Do you know if that refers to the arrangement between Upsher-Smith and Schering?

A. No, I -- I don't know. At the date of this document, they already had concluded their deal.

Q. Right, they had already signed a deal with Schering at the date of this document.

A. Right, correct. And that may, once again, have just referred to the U.S.

Q. What's the purpose of an up-front payment in a licensing deal?

A. Well, there are many reasons for an up-front payment. One is for the licensor to get a return for its investment in bringing the product to the stage

where it's going to license it. That's one major reason, but it depends on, of course, the licensor and his objectives.

Q. And you're aware that Schering made all three payments totaling $60 million to Upsher-Smith?

A. I'm aware it made the first one, and I assume contractually it was responsible for the other two and it did that, but I don't know for a fact.

Q. Well, let's just make sure that we've all got that. Let me show you what has been marked as CX 1689. This is a copy -- this is the public version of Respondent Schering-Plough Corporation's Objections and Responses to Complaint Counsel's Revised Second Request for Admissions filed in this case.

I'd like you to turn to page 8, and I direct your attention to request 73, which reads, "Schering made a payment of $28 million to Upsher within 48 hours of the date on which the Schering-Upsher Agreement was approved by Schering's Board of Directors.

"ANSWER: Admitted."

Do you see that?

A. Yes. Now, the answer is from Schering?

Q. Yes, the answer is from Schering.

A. I see that.

Q. The requests are from complaint counsel and the

answers are from Schering.

A. I understand.

Q. Request number 74 says, "Schering made a payment of $20 million to Upsher approximately one year from the date on which the Schering-Upsher agreement was approved by Schering board of directors.

"ANSWER: Admitted."

Do you see that?

A. Yes.

Q. And request number 75, "Schering made a payment of $12 million to Upsher approximately two years from the date on which the Schering-Upsher Agreement was approved by Schering's Board of Directors.

"ANSWER: Admitted."

Do you see that?

A. I see that. So, this answer is saying that Schering did make all three payments.

Q. Yes. Do you know how much Upsher-Smith invested in their product?

A. I saw I believe in Mr. Troup's deposition a reference to at the time they started talking that they had spent up to $14 million. Of course, they were going to have to spend more to get the final documents in order for Schering to proceed. So -- and I saw some project team meetings that I did try to do analysis of

the project team meetings, on what they intended to spend on getting the documents to that point, and it looked like they would be spending a total of about $18 to $20 million.

Q. And would you say $60 million was a fair return on that investment?

A. Well, they're going to want more than what they spent, because spending $20 million on Niacor-SR prevented them from spending $20 million on something else. It's an opportunity cost, again. So, they're going to want some premium over what they spent.

Q. Would you consider $60 million for $20 million investment a fair return for what they spent?

A. I would consider it what was negotiated, and if the two parties felt it was a fair up-front return, then I think there was nothing wrong with it.

Q. If you were looking for a licensing opportunity, a late stage drug licensing opportunity, for a drug to be marketed in Europe, would you check with the general managers at some of the key markets to see if there were any issues that you had missed?

A. Yes.

Q. You're aware, are you not, that Upsher-Smith had been looking to find a European marketing partner for Niacor-SR in 1977 (sic)?

A. I remember seeing a few documents that related to them contacting some companies in Europe.

Q. Do you know that they hired a company called Moreton located in England to help them find a European partner?

A. I saw reference to that.

Q. And Moreton filed periodic reports with Upsher-Smith on how it was doing?

A. I'm not sure I saw those, but I would assume they would have.

Q. Are you aware that Moreton contacted Schering-Plough Limited, a subsidiary of Schering-Plough, and Schering-Plough Limited expressed no interest in the Niacor-SR product?

A. No, but it wouldn't surprise me that they contacted Schering.

Q. Let me hand you what's been marked as CX 839. Again, this is a document from the files of Upsher-Smith Laboratories, and it's been admitted into evidence.

Have you ever seen this document before?

A. I -- I'm not sure. I may have.

Q. Let me direct your attention to the second page of the document. Do you see the listing for Schering-Plough Limited?

A. Yes.

Q. And it says, "Verbally advised as not of interest on 31/1/97"?

A. I see that.

Q. Had you been in Schering-Plough's shoes in 1997, would you have contacted Schering-Plough Limited in order to see why they were not interested in Niacor-SR?

A. Possibly not, and I can tell you the reason.

Q. Okay.

A. The reason is in drugs that have big strategic value to companies, and I had this experience a number of times at Bristol and Squibb, the corporate powers to be have to make decisions sometimes without the local operations, the reason being that the local operations are much more interested in their quarter-to-quarter P&Ls and hesitate to take on new products a lot of times.

Secondly, it was an area in cardiovascular that Schering overseas was not really into. So, I could see the heads of some of the European countries being resistant to this product, and I had many instances where I was told by the president of the pharmaceutical group that -- just ignore or don't ask the European managers, because this is so important strategically

that we have to make it here.

Q. But if you were looking for a licensing opportunity, a late stage drug licensing opportunity, for a drug to be marketed in Europe, wouldn't you be concerned that if you didn't check with the general managers of some of the key markets, there might be some issues you missed?

A. Well, I believe in this case that Mr. Audibert had sent a questionnaire to the -- many of the country managers on Niaspan before they dropped interest in Niaspan. So, the issues raised from that question probably would be exactly the same as the issues for a Niacor are.

Q. Did you ever see any responses to that questionnaire?

A. No, I just saw the questionnaire.

Q. Do you know if Schering-Plough Limited responded to that questionnaire?

A. I do not.

Q. Knowing that Schering-Plough Limited had verbally advised Moreton that they were not interested in Niacor-SR, wouldn't you be concerned that you might be missing something as to not talk to them with respect to why they were turning the deal down?

A. If strategically I was told we need this drug,

then I probably would have kept that as a very low priority thing to do.

Q. Do you know if Mr. Audibert was told strategically, we need this drug?

A. I only know that they -- there are memos indicating that strategically Schering wanted to get into the cholesterol area, and this was one possibility, yes.

Q. Do you know if Mr. Audibert was ever told that strategically they needed this drug?

A. Only that I know he probably read some of those memos, but I don't know whether he was told directly. I wasn't there.

Q. How do you know he read those memos?

A. Some of them I believe he was copied on. I assume he read them, I'm sorry.

Q. But in order for the drug to be a -- this is about being a lead-in to the ezetimibe product. Is that right?

A. Correct, yes.

Q. Now, in order to be a lead-in to the ezetimibe product, you actually have to get the Niacor-SR on the market, right?

A. That's correct.

Q. I mean, they licensed Niacor-SR, right?

A. Who, Schering?
Q. Schering.
A. Yeah, to get it on the market.
Q. And they never did get it on the market, did they?
A. That's what happened retrospectively.
Q. So, it was not useful as a lead-in, right --
A. As it turned out.
Q. -- to ezetimibe?
A. It wasn't.
Q. So, wouldn't you want to know if there was some reason that Schering-Plough Limited turned it down that would prevent it from getting on the market and prevent it from being a lead-in to ezetimibe?
A. I said that that would not be a high priority for me knowing the thinking of the European managers, at least in my experience. That doesn't say if I saw or talked to the head of Schering -- I guess that was UK, I might not have asked them, but I would have given him the opportunity to say no.
Q. Not all drugs do well overseas even if they're marketed in the United States. Isn't that fair?
A. That's true. Some do better, some don't.
Q. Did you do any independent investigation of the likelihood of a successful sustained release niacin

product being marketed in Europe?

A. I'm not sure what you mean by "independent evaluation." I did not do an extended evaluation.

Q. Did you talk to anybody in Europe about it?

A. No.

Q. Did you read the testimony of Mr. Bell of Kos Pharmaceuticals?

A. I don't believe so, no.

Q. Did you read the testimony of Mr. Patel at Kos Pharmaceuticals?

A. No.

Q. I'd like to hand you a document that's marked CX 36, and this is not a document from either Upsher's files or Schering's files. This is a document that I downloaded a few months ago off of the -- Schering's web page, and it has been admitted into evidence, and it shows cardiovascular product sales for a number of products for 2000 and 2001.

Do you see that?

A. Yes.

Q. And are you familiar with the product K-Dur?

A. Well, I know it's a potassium product. I don't know much about it.

Q. Are you aware it was the subject of the patent litigation between Schering and Upsher-Smith?

A. I believe I knew that, yes.

Q. Okay. Now, according to this document, in the year 2000, there were approximately $287 million in sales of K-Dur in the United States. Do you see that?

A. I see that.

Q. And there were only $3 million worth of sales of K-Dur internationally, excluding the United States. Do you see that?

A. Correct.

Q. Do you know why K-Dur would sell well in the United States and not overseas?

A. Well, there may be many reasons. I'm not sure I'm familiar enough with the product to know exactly why. I believe K-Dur is an RX product that doesn't have a lot of competition yet in the U.S., but I don't know the situation in the overseas market.

Q. How do you know Niacor-SR wouldn't turn out to be just like K-Dur, where it was successful in the United States and not successful overseas?

A. What I know, it really didn't matter in this deal. It's what was projected by the Schering experts for their company, and that's what was important.

Q. But you have no basis for making an independent determination of that. Is that fair?

A. Correct. I probably should add that I imagine

there's a big price difference, so that volume might be different than comparing sales.

Q. Now, did you see any indication in the documents you went through that Upsher-Smith ever completed putting together the results of its two pivotal studies to give Schering?

A. Schering got results from one study, I believe the 115. The 221, they got summary data, but I never saw that they ever received the final report.

Q. Do you know why they never received the final report?

A. No, I do not.

Q. I have a question about CX 1042, which is tab 1 of your notebook.

A. Um-hum.

Q. Do you have your notebook?

A. Yes, I have it.

Q. And my question is about the page that you referred to this morning, SP 1600079.

A. 79?

Q. Yes.

A. Okay.

Q. Now, the final study report is -- if I'm reading this correct, the one protocol, 920115, the final study report was complete. Is that right?

A. At the date this was put together, yes.
Q. Okay. Do you know when this was put together?
A. No. I know Schering got it early in June, but I don't know when --
Q. So, it was put together before early June?
A. Sometime before.
Q. Do you know when actually Schering got these documents and started their analysis?
A. No. I think the final study reports from 115 and 221 are summarized in this document. I think they -- Schering was waiting for the integrated summaries, which were due in October, because the integrated summaries pull together all the data and make it easier for a filing document and easier to submit than the individual ones.
Q. When you say integrated summary, is that the document that is ISS/ISE?
A. That's right.
Q. That's the integrated --
A. Integrated safety and efficacy summary.
Q. And so that would be an integration of both studies?
A. All the data essentially they had at that time.
Q. And that was scheduled for October 1997.
A. Correct.

Q. When -- do you know when Schering stopped working on this project?

A. No, not for sure, but I -- as I went through some of the documentation, it appeared that they slowed down at least or lost interest in the spring of '98.

Q. Schering lost interest in the spring of '98?

A. Well, they weren't getting information. So, at least there were no documents that I saw after that.

Q. And that was before the second payment to Upsher-Smith. Is that right?

A. I imagine it would be, yes.

Q. Let me show you a document that's marked CX 1683. This is a document from the files of Upsher-Smith. This is not in evidence, but this was shown to Dr. Levy during his cross examination.

Have you ever seen this document before?

A. I don't remember it.

Q. Have you ever seen --

A. It's possible.

Q. -- have you ever seen documents from Clintrials Research, Inc.?

A. I saw documents indicating Clintrials Research was a CRO, contract organization working for Upsher-Smith.

Q. Okay. And this is -- if you'd turn to the

second page, it bears the number 093789.

A. Correct.

Q. Do you see the numbers of the protocols listed?

A. Yes.

Q. And these are the protocols that relate to Niacor-SR. Is that right?

A. That's correct, the 115 and 221 were the pivotal studies.

Q. And 994 is one of the continuation studies?

A. I believe so, yes.

Q. And 837 is the other continuation study?

A. I believe so.

Q. And then it also talks about the ISS, and that's the integrated study for 115 and 221?

A. I -- you'll have to point that out to me.

Q. I'm sorry, on the third page. I apologize.

A. The last page -- oh, yes, number -- Roman numeral IV on the last page.

Q. Yes, Roman numeral IV, ISS.

A. Yeah.

Q. And that's the integrated study you were talking about?

A. Right.

Q. And this document is dated in March of '98. Do you see the line in there that says, "USL's European

partner has decided not to proceed with the drug"?

A. Yes.

Q. Do you know what that's about?

A. No idea.

Q. Do you know if Upsher-Smith -- if Schering had decided not to proceed with the drug by March of 1997 -- 1998?

A. March of '98? No, I saw no reference to that.

Q. You just don't know what that refers to?

A. No.

Q. At least by the fall, though, 1998, Upsher had told Schering they weren't going to continue working on the drug. Is that right?

A. Yes, that's correct.

Q. And at least one payment was then made after that time from Schering to Upsher. Is that right?

A. That would be the final payment.

Q. Yes.

A. I believe that's afterwards, yes.

Q. And these payments, because they were noncontingent payments, Upsher-Smith was not obligated to use the money they got from Schering to complete the research on Niacor-SR. Is that right?

A. That's correct.

Q. Had the agreement between Upsher and Schering

instead called for some portion of that money, that $60 million, to be used to fund research to complete the Niacor-SR studies and to prepare reports, then Schering would have had some assurance that the money would have been used for that purpose. Is that right?

A. That's a complex question. If the agreement had stated -- let's see if I can repeat your question -- if the agreement had stated that Upsher-Smith was required to use the actual money that Schering was paying them to -- for -- only for Niacor-SR, yes, they would have to do work on Niacor-SR or not take the money, but the agreement did not state that.

Q. Right. You had mentioned a minute ago that Mr. Audibert had sent out a survey to the European companies' --

A. Managers.

Q. -- managers. Do you remember that?

A. Yes.

Q. Have you seen that survey?

A. I believe I did, yeah.

Q. Let me show you what's been marked as CX 544, and this is a document that came from Schering-Plough.

Is this the survey that you recall seeing?

A. I think so, yes.

Q. Do you see the third paragraph on the page -- first of all, your understanding is this survey is about the Niaspan product, right?

A. That's correct.

Q. And the third paragraph, do you see the last line where it says, "It could be on the European market by mid 1998"?

A. Yes.

Q. Is that consistent with the entry date of competition that Mr. Audibert used in his commercial assessment of Niacor-SR?

A. No, it is not.

MR. EISENSTAT: May I have a moment, Your Honor?

JUDGE CHAPPELL: Yes.

(Counsel conferring.)

BY MR. EISENSTAT:

Q. In your direct examination, you talked about the commercial opportunity that a sustained release niacin offered in 1997. Do you remember that?

A. Yes.

Q. Are you aware that Niaspan's sales have now reached $100 million in the United States?

A. Last year, I believe that's correct.

Q. Do you know why Niaspan has not been able to

find a marketing partner in Europe or Kos has not been able to find a marketing partner for Niaspan?

A. No, I just don't know. They may not have tried or they may have been asking for terms that were too rough. I don't know.

Q. Did you read any of the documents produced in this case from companies in Europe that rejected the Kos product?

A. I remember seeing a few documents from European companies. One was from a company that had indicated some interest, I think, in the product, Pierre Fabre I think. I don't know that I read much on company -- on reasons that companies rejected it.

Q. But you don't know why they haven't been able to find a partner yet in Europe?

A. Kos?

Q. Kos.

A. I have no idea that they're trying.

Q. Do you know if their product is approved in any European countries?

A. There may be one country that it's approved in, but I don't remember. It certainly isn't approved in -- broadly in overseas countries that I know of.

Q. In your notebook, you referred this morning to a document labeled SPX 235. Do you recall that?

A. Yes.
Q. Do you know who wrote that document?
A. No, I don't think so. It was -- I saw it as a separate document, and just -- I assumed it came from Upsher-Smith, but I'm not even sure about that.
Q. The document on the first page bears the date 23 June 1997. Do you see that?
A. I see that.
Q. That date is after Mr. Audibert completed his commercial assessment. Is that correct?
A. I believe that's correct. It's after that but before the Schering board approved it, yes.
Q. Do you know of any evidence that would indicate the Schering board saw this document?
A. I don't know.
Q. Did you read any of the depositions of the Schering board members taken in this case?
A. No, I did not.
Q. Did you see the memorandum sent to the Schering board members prior to the meeting concerning this matter?
A. Yes, I did.
Q. Let me show you what's been marked as CX 338, and again, this is a document from the files of Schering-Plough that has been admitted into evidence in

this case.

A. Yes, I believe I've seen this document.

Q. When you saw this document, did you see any mention of the product ezetimibe in here?

A. I don't remember. I'd have to look through it. I -- it pretty well just describes the deal for Niacor-SR and some background on cholesterol-lowering products.

Q. You don't see any reference to ezetimibe?

A. No, although I would think the Schering board would know all about ezetimibe at this point in time. I can't find, just skimming it, any reference.

Q. But you didn't read the board of directors' depositions?

A. No, I did not.

Q. When you talked about a strategic value to a product, you talked about the use of -- the possible use of Niacor-SR as an entre into the cardiovascular area for Schering for ezetimibe. Is that right?

A. Well, the cardiovascular area, specifically the lowering of cholesterol area, correct.

Q. Could another strategic value be -- for entering into this licensing agreement with Upsher-Smith be to get Upsher-Smith to settle their patent lawsuit and protect the position of the K-Dur

product in the marketplace?

A. I would have no way of commenting on that. I saw --

MR. GIDLEY: Objection, Your Honor. The question is vague and calls for speculation by this witness and lack of foundation.

JUDGE CHAPPELL: I'll overrule it to the extent he has knowledge and can answer it.

THE WITNESS: I saw no documentation speaking to this issue at all at that time, and I'd have no way of making that judgment. I guess I can also add that looking at the deal the way I did and with all the information I have, it was a reasonable deal for Schering to do based on the economics, and that's a certainly good enough reason to do the deal.

BY MR. EISENSTAT:

Q. Now, you said you saw the memo that was sent to the board of directors, CX 338. Is that right?

A. Yes.

Q. I'd ask you to turn to the page marked SP 1200270.

A. Yes.

Q. Do you see under Payment Terms the memo reads, "In the course of our discussions with Upsher-Smith they indicated that a prerequisite to any deal would be

to provide them with a guaranteed income stream for the next twenty-four months to make up for the income that they had projected to earn from sales of Klor Con had they been successful in their suit."

Do you see that?

A. I see that sentence, yes.

Q. And you're aware that the Klor Con product is the generic version of the K-Dur product?

A. I believe so, yes.

Q. Reading that sentence again, let me ask the question, could settling the patent suit be a strategic value for Schering in accepting this license deal?

A. Well, I -- I have a hard time answering that, because I don't know any of the background, and the fact that Upsher-Smith wants something doesn't mean that Schering has to give it to them for that reason. So, I can't really answer your question.

MR. EISENSTAT: I have no more questions, Your Honor.

JUDGE CHAPPELL: Redirect?

MR. RAOFIELD: Yes, Your Honor. I don't know if now would be a good time to take the mid-afternoon break --

JUDGE CHAPPELL: No, we are going to finish this witness.

REDIRECT EXAMINATION

BY MR. RAOFIELD:

Q. Dr. Horovitz, I'm going to begin where complaint counsel just ended with the Schering board of directors document that he was just talking to you about.

A. 338?

Q. Yes, where he read to you a sentence from that document but didn't read you another part that I'd like you to take a look at. It's on SP 120268.

A. Um-hum.

Q. And it's the second paragraph that begins with, "In connection with settlement discussions."

Do you see that paragraph?

A. Yes.

Q. And do you see the last sentence there, "Upsher-Smith also informed us that they were beginning to search for a partner to register and market these four products outside of the United States, Canada and Mexico"? Then there's a section that's been redacted, and it says, "we informed them that any such deal should stand on its own merit independent of the settlement."

Do you see that language?

A. I see that.

Q. Now, complaint counsel asked you if this document was consistent with supporting the proposition that Schering was gaining a strategic advantage in settling the patent suit. Was that sentence inconsistent with that theory?

A. That sentence would indicate that Schering was looking at this deal just for the economics of the Niacor-SR deal, yes, at least that's what they were saying.

Q. And Dr. Horovitz, do you have an opinion, having reviewed all the information that you've relied upon in forming your opinions, as to whether or not the deal for Niacor-SR did stand on its own two feet?

A. Yes, I believe I said that a number of times, that the economics of that deal based on their protections and knowledge -- projections and knowledge at that time would make the Niacor-SR deal a good one for Schering and would stand on its own two feet.

JUDGE CHAPPELL: Doctor, I need you to listen to the question. That question required a yes or no answer.

THE WITNESS: I'm sorry.

JUDGE CHAPPELL: You may proceed.

MR. RAOFIELD: Thank you, Your Honor.

BY MR. RAOFIELD:

Q. You can put that document aside, Dr. Horovitz.

I am going to turn your attention to the binder, the document SPX 235, and on this document I believe -- I wasn't sure I heard correctly, but I believe you testified that you had seen this document and you weren't sure but it may have been produced by Upsher.

A. Correct.

Q. Now, I want to direct your attention to the bottom of SP 160003.

A. Yes.

Q. If I can zoom in on this.

Now, the prior pages of this document have it dated as June 23, 1997, correct?

A. They're all dated that, I think.

Q. And this page appears to have -- this is directly below the section that you had talked about in your direct testimony --

A. Oh, yes.

Q. -- about the strategic value with ezetimibe.

A. Yes.

Q. And do you see where it says, "Kapur," seems to have a file name?

A. Yes.

Q. And it says "Kapur."

Are you familiar with who Mr. Kapur is?

A. Yes, he was the president of Warrick Labs, which is a wholly-owned subsidiary of Schering.

Q. Of Schering. We're done with that document.

A. All right.

Q. The next document I'll ask you to take a look at that complaint counsel questioned you about was the March 14th, 1997 -- it's labeled at the very bottom right CX 544, and you may be able to just look on your screen.

A. I have it, I have it.

Q. Okay. And complaint counsel showed you the sentence that I'm putting up here by Mr. Audibert when he was asking the subsidiaries the question about Niaspan. "It could be on the European market by mid 1998."

A. I see that.

Q. And do you remember being asked about this a moment ago?

A. Yes.

Q. Now, complaint counsel asked you if this was inconsistent with Mr. Audibert's assumption in June of 1997 that Kos -- that Kos would -- or another competitor would enter the market in 2002.

A. Correct.

Q. Do you remember that?

As you read this document, does -- is this document consistent with Mr. Audibert's assumption at this time that Schering enters into a co-marketing arrangement or other deal with Niaspan -- with Kos for Niaspan?

MR. EISENSTAT: Objection, Your Honor, it's leading.

JUDGE CHAPPELL: Overruled. He didn't suggest an answer.

You may answer it, Mr. -- or Doctor, sorry.

THE WITNESS: Thank you.

Well, there were documents I saw that Kos was saying the product could be on the European market in six months; however, I believe those same documents indicated that they didn't have any plans to move ahead in Europe because they were concentrating only on the U.S. market at that time.

BY MR. RAOFIELD:

Q. And with respect to this document, which was sent by Mr. Audibert on March 14th, 1997, what is your understanding of the purpose of Mr. Audibert's memo?

A. Well, it was to solicit input from the operations on a niacin SR product, going into questions on reimbursement, possible sales, level of interest, et

cetera.

Q. And this was as part of Mr. Audibert's involvement with the evaluation of the niacin product should Schering enter into an agreement with --

A. An agreement for overseas markets, yes.

Q. Do you know if in June of 1997, when Mr. Audibert made his assumption that competition would enter in 2002, still had as an assumption that Schering would be entering into a -- some sort of licensing agreement or co-marketing deal with Kos for Niaspan?

A. No, that was already rejected by that time.

Q. We can put that document aside.

In your binder, there's a document SPX 72, if we could turn to that document.

A. 72, right.

Q. Once again, this is a document that complaint counsel was questioning you about a few minutes ago. Do you recall that, Dr. Horovitz?

A. Yes.

Q. And do you recall complaint counsel pointing you to one of the pages on this document and asking you whether that page indicated dosing with an evening meal versus dosing at bedtime?

A. Yes.

Q. I direct your attention to -- again, this is

the page that we had talked about in your direct testimony which was missing the stamp. It's -- it would be after -- it would be the third page in the document after SPX 1600114, so the number for this page, which appears to be missing, would be 115.

A. It starts with, "Introduction"?

Q. It starts with "Introduction," yes.

A. Okay.

Q. Do you have that page?

A. Yes.

Q. And I direct your attention to the bottom of that page and the sentence, in fact, carrying over onto the next page, which says, "There may be some benefit in once a day bedtime dosing since this correlates --" do you see at the bottom of that page where it says, "There may be some benefit in once a day bedtime dosing"?

A. Correct.

Q. Is that consistent with this protocol suggesting bedtime dosing?

A. Yes, I believe so.

Q. We can put that document away.

Dr. Horovitz, complaint counsel also showed you a number of documents, communications between Upsher-Smith and the FDA, about a pharmacokinetic

study. Do you recall that?

A. Right, I do.

Q. And those were documents communicating about the requirement that Upsher-Smith perform a PK study in order to -- as part of its filing for Upsher, and these communications were in early 1997, correct?

A. Yes. There were documents describing the back and forth on designing and developing a protocol.

Q. Have you seen any evidence in this case which would suggest that Upsher-Smith, at the time of the Upsher-Schering deal, had built into its December '97 estimate of when the NDA would be filed completion of that PK study?

A. Yes, I believe they had in their earlier -- some earlier documents had -- before June had projected starting that study about the summer and completing it in time to file with the NDA. That did not happen, but that was their projection.

Q. So, this was after the communications with the FDA but before --

A. Correct, early summer.

Q. -- the license agreement in June that --

A. I believe that's correct.

Q. And at that point -- by that point, Upsher-Smith had built into its timetables completion

of the PK study such that the filing would take place in December of '97?

A. Yes, that -- that would have been very tight, but it could have been done.

Q. And did you see evidence that Upsher-Smith had built that into their timetables?

A. Yes.

Q. Now, complaint counsel showed you a document that related again to the discussions between Schering and Kos regarding the Niaspan product.

A. And the number?

Q. It was CX 540 dated February 11th, 1997.

A. Okay.

Q. And complaint counsel directed your attention to the page 2804, which at the top says, "Preliminary Labeling Indications for Niaspan."

A. Yes, I --

Q. Do you recall that?

A. I have it.

Q. And specifically referred you to the fourth and fifth indications for Niaspan, the fourth one being, "Reduction of recurrent myocardial infarction (MI) in patients with a history of MI," and the fifth one was, "Slowing progressive arthrosclerotic disease in patients with a history of coronary artery disease when

used in combination with bile binding resins."

A. I remember that.

Q. Do you remember that?

And first of all, I'd like to ask you if you can make out what this handwritten note says here. It appears to say, "As a result of CARE and FATS study, CLAS & HARP."

A. Yes, I think those are the acronyms for the long-term studies which showed the reduction of recurrent myocardial infarction with Niaspan and some other ones.

Q. Now, were those studies that were done with niacin generally or Niaspan specifically?

A. No, those were done with niacin.

Q. And I believe you stated your opinion that this is consistent with the conclusion that any sustained release niacin product would receive those indications as a result of that.

A. Yes, the FDA, if they accept the premise that a compound, in this case niacin, works in this indication, they would provide what they call class labeling for any niacin-related product.

Q. Okay. And what is class labeling, if you could just state it more clearly?

A. Class labeling essentially says we're going

to -- FDA says we're going to give you the same label for indications for any drug in a class. For instance, the statins have class labeling. You will find differences in the package insert because of side effects or things like that, but primarily the indications are class labeled.

Q. I'm going to show you now a document that you don't have, complaint counsel did not provide it to you. This is another document relating to the communications between Schering-Plough and Kos regarding Niaspan dated April 9, 1997, and I direct your attention to the second page, which lists the same indications that complaint counsel had showed you, and I've highlighted indications number 4 and 5.

Do those appear to be the same number 4 and 5 on the document that they did show you?

A. I believe it's the same wording, yes.

Q. And the paragraph immediately following says, "The last two indications were suggested by the FDA and are based on the results of CARE, CLAS, HARP and FATS studies which confirmed such beneficial effects on niacin as a class."

A. Yes, I see that.

Q. Is that consistent with what you just testified to as to that would apply to any sustained release

niacin?

A. Ah, yes.

Q. And any sustained release niacin would include Niacor-SR?

A. That's correct.

Q. In that same line of questioning, complaint counsel referred you to the draft labeling or the draft package insert, which I believe you have a copy of, for Niacor-SR.

A. Um-hum.

Q. Do you recall that?

A. Yes.

Q. And they directed -- complaint counsel directed your attention to the section of this document of indications and pointed out that the two indications we've been talking about were not listed in that section. Do you recall that?

A. In this document from Upsher-Smith, the June 24, yes.

Q. I'd like to direct your attention to the bottom of the second page in that document, the final paragraph, speaking with respect to --

A. Excuse me, are you talking about the first page after the cover?

Q. Yes, it would be -- it's a little hard to read,

but it looks like it's 3780?

A. Yes, correct.

Q. And it's going to be -- it's going to begin with, "The Coronary Drug Project," and it's the sentence -- let me get this -- focus in on it. It speaks of the Coronary Drug Project in 1975.

Do you happen to know if that was the study that you referred to in your direct testimony or one of the studies you referred to in your direct testimony when you said that niacin as a class was shown to reduce morbidity and mortality?

A. Yes, that is one of those large studies.

Q. Now, the last sentence and carrying over to the next page talking about this says, "Over an observation period of five years, nicotinic acid showed a statistically significant benefit in decreasing nonfatal, recurrent myocardial infarctions."

Do you see that sentence?

A. Yes, I do.

Q. And is that consistent with the class labeling status for all SR niacin products on the basis of the general studies relating to niacin?

A. It would be consistent for all niacin products, including SR.

Q. And specifically, the -- one of the two that we

have talked about, one of the two indications, this is in reference to the one of reducing nonfatal, recurrent myocardial infarction?

A. Yes, I think that was the first one.

Q. Okay. Now, before I move on to the other indication, I just want to clarify, this document is in Upsher-Smith's Niacor-SR --

A. That's correct.

Q. -- in relation to Niacor-SR.

Now, on the bottom of that same page -- if you will give me one second to look for where I saw this -- it refers to -- let me see if I can get it on the screen here. "When compared to conventional measures, intensive lipid-lowering combination therapy significantly reduced the frequency of progression and increased the frequency of regression of coronary arthrosclerotic lesions in patients with or at risk for coronary artery disease."

Do you see that?

A. Yes.

Q. And do you see the reference to the FATS study?

A. FATS, F A T S.

Q. And I believe there's the CLAS study there also?

A. Right.

Q. And where this says, "reduced the frequency of progression and increased the frequency of regression of coronary arthrosclerotic lesions in patients at risk for coronary artery disease," is that consistent with the other indication that complaint counsel directed your attention to?

A. The second one that talks about arthrosclerotic disease, yes.

Q. And again, this information is contained in the 1996 Upsher draft labeling, the first document that we just --

A. It's contained in this document, yes.

Q. Which is -- relates not to Niaspan but to Niacor-SR.

A. That's correct.

Q. And my final question on that point, just to tie up this issue, again, we have the reference to the CLAS and FATS studies in this document?

A. Yes.

Q. And going back to the original document, which complaint counsel showed you, there was that -- the matter of that handwritten note which specifically said that this was "as a result of CARE & FATS study," do you see that, and then it references the CLAS and HARP studies?

A. Correct.

Q. And these would be the same studies referenced in the Upsher document for Niacor-SR?

A. That's right.

Q. Dr. Horovitz, you were asked a question about K-Dur during your cross examination. Do you recall that?

A. I believe so, yes.

Q. Have you done any study in connection with this case or otherwise of the potassium chloride market and the market for K-Dur and potassium chloride products?

A. No.

Q. The final section I'd like to discuss with you relates to two documents that complaint counsel showed you relating to Upsher-Smith and the cross-license between Upsher-Smith and Kos Pharmaceuticals in early 1997.

MR. EISENSTAT: I believe that's an in camera document.

MR. RAOFIELD: Oh, excuse me, Your Honor, I forgot that this was an in camera document that we need to go in camera for.

JUDGE CHAPPELL: Okay, I am going to have to ask the public to leave the courtroom. We are going to consider some in camera or privileged information. You

will be notified when you're free to come back into the courtroom. Thank you.

(The in camera testimony continued in Volume 16, Part 2, Pages 3882 through 3888, then resumed as follows.)

CROSS EXAMINATION (cont)

BY MR. GIDLEY:

Q. Dr. Horovitz, I direct your attention to this document that Mr. Eisenstat was working with you on, CX 839. Do you still have that among the papers up there at the podium, the witness stand?

A. I should. Yes.

Q. May I direct your attention, sir, to the second page, and sir, you were asked a series of questions by Mr. Eisenstat, were you not, about this document?

A. I was asked a few, yes.

Q. And in particular, Mr. Eisenstat directed your attention, did he not, to the line referring to Schering-Plough Limited? Is that correct?

A. Correct.

Q. And this document advises as of what date that there was "not of interest" by Schering-Plough Limited?

A. The 31st of January, 1997.

Q. Why don't you set that aside.

I'd like to show you another document I've only

got one copy of, sir, so just look for it on your ELMO. I'll start with identifying it.

I'll represent to you, sir, it's USX 162. I'll try to make this as legible as possible. Sir, would you read into the record the date at the upper right-hand corner?

A. I believe it is 1 February 1997.

Q. Let me zoom in a little more for you.

A. Yes, that's clearer. Oh, 3, 3 February 1997.

Q. 3 February 1997. And on what letterhead does this document appear?

A. Schering-Plough Limited.

Q. Is that the same entity that was on the prior document?

A. I would assume so, yes.

Q. Can you refer back to the exhibit that Mr. Eisenstat handed you, CX 839?

A. Yes.

Q. And directing your attention back to the document we just had on the ELMO, I'll put it back up, what was the Schering-Plough entity that he was asking you questions about?

A. Schering-Plough Limited.

Q. All right. And that's the same as in USX 162, is it not?

A. The one you have up there, yes, Schering-Plough Limited.

Q. And this letter is signed by whom, sir?

A. Dr. Jackie Harris, business development director.

Q. For what company?

A. I assume of Schering-Plough Limited.

Q. And sir, directing your attention to the first paragraph, Niacor-SR, "Peter's response was for the UK. I did actually pass on details to our International Division, but, to date, have not had a response."

Do you see that language?

A. I do.

Q. Now, sir, does this post-date CX 839, the document that Mr. Eisenstat showed you?

A. Yes, by about four days.

Q. And as of February 3rd, 1997, sir, what was the status within Schering-Plough of Niacor-SR at this time?

MR. EISENSTAT: Objection, Your Honor, beyond the competence of the witness what the status was of Niacor-SR.

MR. GIDLEY: Your Honor, the door is wide open. This is a cross examination line that Mr. Eisenstat opened. If this witness has no knowledge of these

marketing efforts, then it was not a proper subject for cross examination in the first place.

MR. EISENSTAT: The current question didn't go to the marketing efforts; the current question went to the state of mind of Schering-Plough Limited and the International Division. How can he know what their state of mind is?

MR. GIDLEY: The cross examination, Your Honor, if I may, went directly to what was Schering-Plough UK doing with David Pettit's marketing efforts in late January 1997. Now, four days later, we have a subsequent document which Mr. Eisenstat did not show the witness. I think we're entitled to hear the witness' reaction to this document.

JUDGE CHAPPELL: So, you're asking him what the status was based on his interpretation of this document?

MR. GIDLEY: Yes, Your Honor. This expert, like many other experts, has had to rely on business records.

JUDGE CHAPPELL: I'll allow it. You can answer it. I'll overrule the objection. I'll give it the weight it deserves.

THE WITNESS: Well, my interpretation from what I read is that Peter, whoever Peter is, has sent some

response for the UK company but that the International Division -- and in most companies, the UK division would report to the International Division -- has not done their analysis or at least hasn't responded.

BY MR. GIDLEY:

Q. As of the date of USX 162. Is that your interpretation?

A. As of the date 3 February '97, yes.

Q. Let me direct your attention to CX 338, the Schering-Plough board of directors memo. Do you recall this document, sir?

A. Yes, I believe I have it here.

Q. And it's for the record CX 338, is it not, sir?

JUDGE CHAPPELL: Let's give him time to retrieve the document, Counselor.

THE WITNESS: Let me get it out. It's the last one in the pile, CX 338.

BY MR. GIDLEY:

Q. Yes, sir.

A. I have it.

Q. Let me direct your attention -- sir, is this a document that you've reviewed in connection with your preparation for testimony in this case?

A. I did.

Q. Sir, directing your attention to the last page,

I've put that up on the ELMO.

A. Yes, I've got it, okay.

Q. Sir, in your professional opinion in reviewing the facts that you have before you, do you have any reason to believe that the economic value of $225 to $265 million calculated on this page was an intentionally false or fraudulent statement on behalf of Schering-Plough as of the date that it was made?

A. No, because it matches pretty closely to my analysis done separately without having seen this.

MR. GIDLEY: No further questions, Your Honor.

JUDGE CHAPPELL: Recross?

MR. EISENSTAT: Just very briefly, Your Honor.

JUDGE CHAPPELL: You may proceed as soon as Mr. Gidley's clear.

RECROSS EXAMINATION

BY MR. EISENSTAT:

Q. Could you hold onto that document?

A. This one? Yes.

Q. That's CX 338?

A. Correct.

Q. Could you turn to the third page of the document again, it bears the number SP 120268?

A. 68? Yes.

Q. Do you see that? That's the one you were just

asked about briefly.

A. I see it.

Q. And do you see the part of the sentence you were asked about, "we informed them that any such deal," et cetera? Do you see that line?

A. Yes.

Q. And do you see above there there's a line that's been redacted, that is, Schering-Plough declined to let anyone else see what that was? Do you know what that line says?

A. I have no idea.

MR. EISENSTAT: I have no more questions, Your Honor.

JUDGE CHAPPELL: Anything further?

MR. RAOFIELD: Nothing for Schering-Plough, Your Honor.

MR. GIDLEY: No, Your Honor.

JUDGE CHAPPELL: Thank you, Dr. Horovitz, you're excused.

Who's up next?

MR. CURRAN: Your Honor, Upsher-Smith has a witness to call.

JUDGE CHAPPELL: What's your anticipated time for this witness?

MR. CURRAN: I anticipate the direct exam to

last between half an hour and 40 minutes. He is an out-of-town witness, Your Honor.

JUDGE CHAPPELL: You realize this is February 14th. We don't want to cause any relationship discord by going late into the night.

MR. CURRAN: Your Honor, I think this witness can go and we can all be comfortably at our homes by the proper dinner hour.

JUDGE CHAPPELL: Mr. Eisenstat, are you handling the cross?

MR. EISENSTAT: Mr. Kades will do the cross.

JUDGE CHAPPELL: Do you have a ballpark estimate of the length of your cross?

MR. KADES: Well, Your Honor, after Mr. Nields got it on the nose yesterday, I feel like the pressure's on, but --

JUDGE CHAPPELL: The bar is very high now.

MR. KADES: I know. I can't imagine that my cross would be more than 30 minutes, and it may be shorter, but I've got a built-in window.

JUDGE CHAPPELL: I just wanted to get an idea if we were in for another night where people had to be let out the side door. It looks like we can manage it.

Why don't we take 15 minutes. We will recess

until 4:35.

MR. CURRAN: Thank you very much, Your Honor.

(A brief recess was taken.)

JUDGE CHAPPELL: Mr. Curran, you have a witness to call?

MR. CURRAN: Yes, Your Honor.

This next witness served as outside counsel to Upsher-Smith during the litigation, the patent infringement litigation with Schering and with the ensuing settlement discussions, and he's appearing here today to testify as to nonprivileged matters. He appeared in the same manner at a deposition and was -- and gave full testimony there.

Accordingly, at this time, Upsher-Smith calls Nicholas Cannella.

JUDGE CHAPPELL: Raise your right hand, please.

Whereupon--

NICHOLAS M. CANNELLA

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

JUDGE CHAPPELL: Thank you, have a set.

State your full name for the record, please.

THE WITNESS: Nicholas M. Cannella, C A N N E L L A.

JUDGE CHAPPELL: Thank you.

DIRECT EXAMINATION

BY MR. CURRAN:

Q. Mr. Cannella, are you employed?

A. I'm a partner at the Fitzpatrick, Cella, Harper & Scinto law firm.

Q. Where is that law firm located?

A. We have offices in three cities, New York, Washington, D.C. and in Orange County, California. I'm in the New York office.

Q. Sir, does the law firm Fitzpatrick Cella have a specialty?

A. Yes, we specialize in intellectual property matters and related subject matter.

Q. And how big is the firm?

A. About 150 lawyers.

Q. Do you personally have a specialty?

A. Intellectual property litigation, patents and trademarks.

Q. Do you focus in any other areas, any experience in other areas?

A. Well, I've been at Fitzpatrick Cella for the last 16 years. Prior to that I was at Simpson Thatcher trying general commercial cases, including antitrust cases, and I work in the antitrust field as it relates to intellectual property matters in my current

position.

Q. Very good.

Does your practice focus on any particular industries?

A. I litigate in any industry that clients ask me to litigate in, but I have litigated in the pharmaceutical industry extensively and also in the electronics industry.

Q. Okay. Sir, did there come a time at which you were contacted by Upsher-Smith or a representative of Upsher-Smith to represent them in connection with patent infringement litigation?

A. Yes.

Q. Okay. Can you please explain the circumstance of that contact?

A. Yes. I believe the contact was December of '95 or January of '96, I received a telephone call from Mark Robbins at Upsher-Smith asking if my firm and I were available to represent it in connection with a patent infringement action that had been brought against it by Key Pharmaceuticals or Schering-Plough relating to an ANDA application that Upsher-Smith had filed.

Q. Did Mr. Robbins say why he was contacting you and your firm?

A. Yes. As I understood it, Upsher-Smith's regular patent counsel was the Merchant & Gould firm in Minnesota, but a conflict had arisen, and Merchant & Gould was not available to Upsher-Smith. Mr. Robbins had gotten my name through a number of sources as a recommendation, someone who may be able to help him out.

Q. Sir, do you know the nature of the conflict that Merchant & Gould had?

A. I do. As I recall it, a then Merchant & Gould partner had in a prior employment as an associate at another firm been involved in some capacity in the prosecution of the Schering-Plough patent that was the subject of the litigation, and Schering-Plough asserted that as a conflict so that Merchant & Gould felt it was not able to proceed in the litigation.

Q. So, Merchant & Gould was forced out of the representation. Is that correct?

A. That is correct.

Q. Sir, were you and your firm ultimately retained by Upsher-Smith?

A. Yes.

Q. Sir, you've described the lawsuit a little bit. Do you recall where it was?

A. It was in the District Court in Newark, New

Jersey, before Judge Walls.

Q. And sir, after being retained, did you have primary responsibility for the defense of that case?

A. I did not. I explained to Mr. Robbins when he visited us that I was at that time fairly heavily engaged in other litigations. I had with me one of my partners, Bruce Haas, and Upsher-Smith agreed to retain us and have Bruce have the day-to-day responsibility in the case, and I would serve in a senior adviser capacity to the extent my time allowed.

Q. And did you, in fact, serve in that capacity going forward?

A. I did.

Q. Were you kept informed of the status of the litigation?

A. I wouldn't say that I was kept informed on a day-by-day, every development in the case capacity, but I was visited by Bruce from time to time and given background on issues that he was facing so that he could ask my opinion as to how to proceed.

Q. Now, sir, that litigation ensued for how long?

A. Well, as I say, I believe the lawsuit itself started in either December of '95 or January of '96, and it was ultimately settled in June or July of '97.

Q. So, roughly 18 months?

A. That's correct.

Q. Sir, I know you didn't have day-to-day responsibilities, and I don't want a tremendously detailed answer on this, but can you describe in general terms the course of the litigation during those 18 months?

A. I would describe it as a vigorously contested litigation by both parties. In fact, it started with a motion right out of the box not only relating to the Merchant & Gould disqualification but potentially involving the disqualification of Upsher-Smith's FDA counsel, the Hyman Phelps firm, and a motion to preclude my firm from getting any work product from the Merchant & Gould firm because of some fruit of the poisonous tree type argument.

Q. All right, sir, separate and apart from disqualification issues and so forth, how did the litigation proceed?

A. As I said, it was vigorously contested. There were -- there was a great deal of discovery. There were many discovery battles, as I recall it, and both parties contested the litigation with vigor, leading up to our filing of a summary judgment motion on noninfringement grounds and then a subsequent summary judgment motion on inequitable conduct grounds in the

procurement of the patent.

Q. Sir, do you recall when you filed at least the first summary judgment motion?

A. I believe the noninfringement summary judgment motion was the first of the two that was filed, and my best recollection is that it was filed at the end of 1996.

Q. Was that argued?

A. Eventually it was. One of the frustrations in the case was that Judge Walls did not hear argument on the summary judgment motion, I think he scheduled it on one or even more than one occasion and then put the argument off. It was eventually argued on the day before the trial itself was to commence.

Q. Sir, was the summary judgment motion -- were either of the summary judgment motions ever granted?

A. No.

Q. Sir, have you ever heard of a gentleman by the name of Dr. or Dean Gilbert Banker?

A. I've never met Dr. Banker, but I know the name. He was an expert that was involved in the underlying patent case.

Q. For whom?

A. Interestingly, for both sides. What happened is we contacted Dr. Banker and asked him if he would be

interested in serving as an expert for Upsher-Smith and sent him some materials. We proceeded in the belief that he was, indeed, interested and would serve as an expert for Upsher-Smith.

Subsequently, at the 11th hour before a scheduled meeting with my partner Mr. Haas and some Upsher-Smith personnel, he called and said he was not interested in serving as an expert for Upsher-Smith, and I believe he even went so far as to then turn up as an expert for Schering-Plough in the case.

Q. Sir, did your firm represent Upsher-Smith for free?

A. No.

Q. In fact, you sent monthly bills, correct?

A. That's our policy, and I assume that the bills were sent in accordance with the policy once a month.

Q. Nothing to be ashamed of, sir.

A. I am not at all.

Q. Mr. Cannella, I'd like to direct your attention to the binder I've placed in front of the witness chair.

Your Honor, I've provided one to the Court and one to complaint counsel and counsel for Schering as well.

Now, Mr. Cannella, I do not want to belabor

this, but I want to draw your attention to the first 19 tabs, and these are all documents that have already been admitted into evidence, so I'm not going to ask you foundational questions and so forth, but I'd like you to identify and confirm that these are, in fact, bills sent by your firm to Upsher-Smith.

Let's begin under tab 1, sir.

A. Yes.

Q. Do you see USX 83 there?

A. I don't, but --

Q. If you look at the bottom --

A. Oh, I'm sorry, now I do, yes.

Q. That's just a reference for this case.

A. That's fine.

Q. And then by the way, the production number to the right of that indicates FitzCella in this case 0075. That just indicates the source of the production.

A. Okay.

Q. Sir, the document under tab 1, USX 83, does that appear to be a redacted bill from Fitzpatrick Cella to Upsher-Smith?

A. Yes, for the time period -- services would have been rendered during the time period January 1, 1996 to January 31, 1996.

Q. And the total on this bill is approximately $31,000?

A. Services and disbursements, correct.

Q. Very good.

Then under tab 2, sir, a similar bill, this time covering the period February 1996?

A. Yes.

Q. And the total of $31,000 and change?

A. That's correct.

Q. Sir, by the way, all of these bills relate to the patent infringement litigation, correct?

A. That is correct.

Q. Okay. Sir, tab 3, do you see USX 85 there?

A. Yes.

Q. And this is the bill for the period of March 1996?

A. Yes, that's correct.

Q. And the total on that bill is $51,000 and change?

A. Yes.

Q. Sir, under tab 4, is that another bill, this time for April of 1996?

A. Yes.

Q. And is USX -- oh, this is actually a continuation of USX 85, I'll note for the record.

The total on that invoice, sir, is $91,000 and change?

A. That's correct.

Q. Under tab 5, do you see USX 86 there?

A. Yes.

Q. And that's the bill for May of '96?

A. That's correct.

Q. And the total is approximately $100,000?

A. That's correct.

Q. Under tab 6, that's the bill for June of '96?

A. Yes.

Q. And the total on this is approximately $102,000?

A. That's correct.

Q. And I don't know if I said that, that's USX 87.

A. Yes.

Q. Under tab 7, sir, that's USX 88.

A. Yes.

Q. And that's the bill for July of '96.

A. Correct.

Q. And the total there is $92,000 and change?

A. Yes.

Q. Under tab 8, sir, that's USX 89.

A. Correct.

Q. That's the bill for August of '96?

A. Yes.
Q. And the total is approximately $163,000?
A. That's correct.
Q. Sir, on tab 9, that's September of '96, correct?
A. Yes, sir.
Q. That's USX 90?
A. Yes.
Q. And the total is approximately $128,000?
A. Yes.
Q. Under tab 10, that's USX 91, correct?
A. Yes, it is.
Q. And that's the bill for October of '96?
A. Yes, it is.
Q. And the total is approximately $165,000?
A. That's correct.
Q. Tab 11, sir, that's USX 93, correct?
A. Yes, it is.
Q. And this is the bill for November of '96?
A. Correct.
Q. And the total is approximately $120,000?
A. Yes.
Q. Under tab 12, that's USX 92, correct?
A. Yes, it is.
Q. And the -- that's for the period of December

'96?

A. Yes.

Q. And the total there is approximately $135,000?

A. That's correct.

Q. Under tab 13, we're into the period January of '97.

A. Yes.

Q. That's USX 94.

A. Yes.

Q. And the total there is approximately $220,000?

A. That's correct.

Q. Under tab 14, sir, that's USX 95, correct?

A. Yes, it is.

Q. Covering the period February 1997?

A. That's correct.

Q. And the total there is approximately $185,000?

A. Yes.

Q. Under tab 15, USX 96?

A. Correct.

Q. That's for March of '97?

A. Yes.

Q. And the total there is $217,000, approximately?

A. That's correct.

Q. Under tab 16, that's the bill for April of '97?

A. Yes, it is.

Q. That's USX 97?
A. Yes.
Q. And the total there is approximately $182,000?
A. That's correct.
Q. Under tab 17, it's USX 99, correct?
A. Yes, it is.
Q. And that's the bill for May of '97?
A. Yes.
Q. And the total there is approximately $340,000, correct?
A. Yes, it is.
Q. And under tab 18, that's the bill for June of '97?
A. That's correct.
Q. And that's USX 100, correct?
A. Yes.
Q. And the total there is approximately $408,000, correct?
A. Yes.
Q. And then under tab 19, that's USX 101, correct?
A. Yes, it is.
Q. And now this is for July of '97, correct?
A. Yes, it is.
Q. And the total there is $28,000 and change, correct?

A. Yes, that's right.

Q. Okay.

Thank you for your indulgence in that, Your Honor.

JUDGE CHAPPELL: You're welcome, Mr. Curran.

BY MR. CURRAN:

Q. Mr. Cannella, did there come a time when you participated in discussions to settle the litigation?

A. I participated in discussions about a business deal between Schering-Plough and Upsher-Smith.

Q. Okay. When did you participate in such discussions?

A. Early June of 1997.

Q. And how did your participation begin?

A. My partner, Bruce Haas, asked me if I could attend a meeting because he had a conflict on his schedule. I agreed, and I went to the meeting.

Q. Sir, did you have any discussions with anybody else prior to the actual meeting?

A. Yes.

Q. Okay. With whom did you have discussions?

A. After Mr. Haas informed me of the meeting, I received a telephone call from a lawyer at Schering-Plough named John Hoffman.

Q. Had you ever heard of him before?

A. I had not.

Q. What did he say?

A. He introduced himself and gave me a little background on who he was and his career. As I recall, he had spent a number of years at one of the bigger firms in New York before going to Schering-Plough, told me that he'd like to discuss the logistics and ground rules for the meeting which he understood I would be attending together with the Upsher-Smith representatives.

Q. Let me back up a little bit.

Do you remember any more details about his introduction of himself?

A. Yes, he told me -- I can't be precise as to the name of the firm. My recollection is that he said he had been at the Cadwalader firm and that he had done antitrust work at the Cadwalader firm. He offered that information because he wanted me to be aware that there were sensitive issues with respect to antitrust in any business deal. I told him that I had been involved in these types of transactions and was aware of the sensibilities.

Q. Sir, you mentioned that --

A. Sensitivities I should say.

Q. -- you mentioned that he discussed logistics

and ground rules.

A. That's correct.

Q. Taking those seriatim, what logistics did he discuss?

A. Well, I think logistics, we just confirmed the time and place of the meeting and who would be attending the meeting from each side. And with respect to ground rules, he told me that this was in Schering-Plough's mind a meeting to discuss business opportunities, that there would be no need for any debate as to the merits of the underlying patent case, and again, mentioned the sensitivities of antitrust considerations.

Q. Did he indicate what business opportunities were going to be discussed?

A. He did not in that telephone call to the best of my knowledge.

Q. Did he indicate why there would not be a debate on patent issues?

A. He did not explicitly tell me why there would not be a debate on patent issues. He did tell me that there would be no one there from Covington, which was handling the patent case for Schering-Plough, and I had the impression from the discussion that the parties had already talked about those issues, and they were not on

the table for discussion at the business meeting.

Q. Sir, is there anything else that you recall from this initial phone conversation with Mr. Hoffman?

A. No, I don't believe so.

Q. Sir, are you sure this call took place?

A. Absolutely.

Q. Are you sure that Mr. Hoffman raised antitrust issues in this call?

A. Absolutely.

Q. Sir, what happened next?

A. The meeting was set for Schering-Plough's facility in New Jersey. I'm not precise as to the town, I think it's Kenilworth. And I had spoken with Mr. Troup just to get logistics squared away with him. I drove to the meeting, and as prearranged, I met Mr. Troup and the gentleman who accompanied him, a fellow whose name was Andrew, and I believe his last name was Hirschberg, although I'm not 100 percent certain. They also drove to the meeting in Andrew's car. We met in the parking lot, had a brief discussion, proceeded into the meeting.

Q. Had you ever met either of them before?

A. I had not. I had spoken with Mr. Troup on the phone I believe during the course of the litigation, but I had never met him in person.

Q. How did you get to the meeting in Kenilworth?
A. I drove my car.
Q. And then did you proceed in from the parking lot into the meeting?
A. I did, after admiring Mr. Hirschberg's car.
Q. What kind of car did he have?
A. It was a Mercedes convertible, and I was driving a Miata.
Q. Sir, who was at the meeting for Schering-Plough?
JUDGE CHAPPELL: Excuse me, sir, the court reporter didn't understand. You were driving a what?
THE WITNESS: A Miata.
BY MR. CURRAN:
Q. And Hirschberg had the Mercedes?
A. Unfortunately, yes.
Q. Who was at the meeting for Schering-Plough?
A. John Hoffman was there. The senior business person was a gentleman whose name I believe was Ray Kapur, and there were I believe one or two other younger business people who I viewed as sort of being there in support of Mr. Kapur.
Q. Have you ever met any of them before?
A. I had not, except my telephone conversation with Mr. Hoffman.

Q. Sir, what happened at the meeting?

A. Well, after the usual exchange of pleasantries and the offer of coffee, it was a business meeting. Mr. Troup and Mr. Hirschberg made a presentation to Schering-Plough as to four or five Upsher-Smith products which Upsher-Smith had at various stages of development, so somewhere in their development pipeline, and explained the status, provided written materials to Schering-Plough with respect to those products, and explained to Schering-Plough why Upsher-Smith felt those products had significant value to Schering-Plough.

Q. Do you remember anything they said specifically about the value of the products?

A. Well, I do recall that Upsher-Smith, and I believe it was Mr. Troup who said it, said that he thought if Schering-Plough took these products over, Schering-Plough should be willing to pay somewhere in the neighborhood of $80 million or slightly above that, and I remember that there was a discussion of that value and how Upsher-Smith had arrived at it.

Q. Do you remember any more details as to how Upsher-Smith justified the $80 million proposal?

A. Well, as I said at my deposition, I can't recall precisely the products that were being

discussed, but I do recall that one of the products being discussed apparently was very similar in nature to a product that another pharmaceutical company, a company called Kos Pharmaceutical, had in the market, and I recall that there was a discussion of the fact that Kos had fairly recently, so contemporaneous to the meeting, gone through some form of transaction, I believe it was described as an initial public offering, based on that product as its primary asset and that Kos had a value of something like $500 million.

Q. Sir, do you remember anything else about what the Upsher-Smith representatives said during the meeting?

A. No, again, all I recall is that they made the points to Schering-Plough that these products were in the pipeline, these products had value and that -- and they -- and in particular I believe they said they would have more value to Schering-Plough because of Schering's resources in bringing them to market and marketing them.

Q. Sir, what was the nature of the written materials you referred to?

A. My best recollection is that it was a booklet of some kind, it might have even been a three-ring booklet, and it had within it sections on each of the

products that were being discussed.

Q. Sir, what did -- well, did you say anything during the meeting?

A. No, I did not.

Q. Did the Schering-Plough people say anything during the meeting?

A. Yes.

Q. What did they say and who said it?

A. Well, my only recollection of anyone speaking on behalf of Schering-Plough was that Mr. Kapur did the speaking on behalf of Schering-Plough, and I would characterize it as a dialogue between Mr. Kapur, as assisted by these other two younger fellows, and the Upsher-Smith representatives inquiring as to the products, their status, et cetera. So, in the nature of a due diligence negotiation kind of discussion.

Q. Do you remember any specific questions that Mr. Kapur asked?

A. I cannot recall any of the specific questions. I do recall there was a fair amount of dialogue on Kos Pharmaceutical and this $500 million for one of these products.

Q. Sir, how long did the meeting last?

A. My best recollection, an hour and a half, two hours, somewhere in that neighborhood.

Q. What did you do after the meeting?
A. Well, the meeting ended with Mr. Kapur on behalf of Schering-Plough saying that they were going -- they, Schering-Plough, were going to continue to analyze the issues and their interest in the products and get back to Upsher-Smith.
Q. That's how it was left at the end of the meeting?
A. That's how the meeting ended.
Q. So, you left.
A. Yeah, we had a -- Mr. Troup, Mr. Hirschberg and I had a brief farewell conversation in the parking lot, and I left.
Q. Okay. What was the next step in the settlement discussions or the licensing business opportunities discussions?
A. My best recollection is that within a day or two, I had another conversation with Mr. Troup and Mr. Hirschberg just sort of reviewing what had happened at the meeting.
Q. All right, let me back up for a second based upon my misspeaking a moment ago, and let me ask, in that meeting in New Jersey at Schering-Plough, was there any discussion of the patent litigation that was pending between these two parties?

A. No.

Q. The only subject discussed was this business opportunity, this possible licensing transaction?

A. A transaction whereby Schering-Plough would acquire rights in certain Upsher-Smith developmental products. It wasn't clear that it would be a licensing transaction or the purchase of patent rights or what. It was just are you interested, at what dollar value, and as I said, Mr. Kapur was clearly aware of these products and knowledgeable about them, asked questions concerning their status, and then it ended with Mr. Kapur saying let us think about it some more and we'll get back to you.

Q. Okay. And what was the next step in terms of your personal involvement?

A. As I said, I got a phone call from Mr. Troup and Mr. Hirschberg within a day or so, and we just sort of reviewed what had happened at the meeting.

Q. What was the next involvement you had in dealing with somebody at Schering-Plough?

A. Either in that phone call that I just mentioned or a subsequent phone call, I was asked by Mr. Troup if I was available to participate in a telephone conference with Upsher-Smith representatives and Schering-Plough representatives.

Q. Did you?
A. I did.
Q. And when did that occur?
A. I would place it within a week of the face-to-face meeting that I've just described.
Q. And what's your recollection of when that face-to-face meeting occurred?
A. As I said, I think it was early June, somewhere in the June 10-11-12 area, something like that.
Q. Okay. So, this is a few days after that?
A. That's correct.
Q. Where were you for this telephone conference?
A. In my office in New York.
Q. Who else was on the line?
A. Well, I know that Mr. Troup and Mr. Hirschberg were on the line from Upsher-Smith's facilities in Minnesota. I also know that there were Schering-Plough representatives on the line. I believe, again, the lead spokesperson for Schering was again Mr. Kapur.
Q. How do you know that Mr. Troup and Mr. Hirschberg were in Minnesota?
A. I think in the phone call when they asked me to participate, they told me that they were both together, and I also had a conversation offline with Mr. Hirschberg while the conference call was going on.

Q. What do you mean by that, "a conversation offline"?

A. Well, during the course of the conversation that was taking place in the conference call, Schering had obviously done some additional due diligence and obviously had expressed sincere interest and was offering I believe something like $60 million to Upsher-Smith to acquire rights to these four products. Upsher-Smith was, as I said earlier, looking for something like $80 million, and as the parties were exploring ways to bridge that gap, the thought -- a thought occurred to me as one of the ways to possibly bridge the gap, but since I had not had the opportunity to make this suggestion to Mr. Troup, I didn't want to offer it in the conference call if it was something that he was not interested in.

Q. Okay, I don't want to get into your private discussion with Mr. Troup, but by offline, you had a separate telephone call --

A. Yeah, I have two lines in my office. I put the conference call on mute and called Mr. Troup's office on my other line, asked Mr. Hirschberg to step out and relayed my idea to him so that he could share it with Mr. Troup.

Q. Okay. Where were the Schering-Plough people to

the best of your knowledge?

A. I truly do not know. They may have -- they may have been in Minnesota for all I know.

Q. What else do you remember about this meeting or conference that you participated in by telephone?

A. Well, as I say, I remember the parties discussing where they were and that there was a gap, a financial gap in terms of doing this business deal I believe of between $60 and $80 million -- I'm sorry, between Schering-Plough's offer of 60 and Upsher-Smith's request for $80 million, and I recall that at one point in the conversation, one of the ways to potentially bridge the gap that was suggested was to include milestone payments in the agreement so that as the products reached certain stages in the countries that were being talked about, additional payments would be made.

Q. That's what you mean by milestone payments?

A. That's what I meant by milestone payments, yes.

Q. You said a moment ago that you thought that the Schering-Plough people or Mr. Kapur had done some additional due diligence, right?

A. Yes, I did.

Q. What's your basis for saying that?

A. They certainly were knowledgeable -- I'm

neither an expert in the pharmaceutical industry, nor am I an expert in valuing products, but Mr. Kapur and his -- well, he was the only spokesperson, but Mr. Kapur certainly was asking pointed questions and talking about specific values in specific countries, as I recall it.

Q. How did that meeting or conference conclude?

A. No agreement was reached during the course of the telephone conference, but again, I believe it was left that the parties would continue to talk with each other about the possibilities of doing this deal.

Q. At this meeting or conference, was there any discussion of the patent case that was going on between the two companies?

A. No.

Q. What was your understanding as to why that wasn't a subject of discussion at this telephone conference or at the earlier meeting in Kenilworth?

A. Again, consistent with the impression I had from prior to the Kenilworth meeting, I believe the parties had resolved those issues in principle at least, so they were off the table and they were only talking about business.

MR. KADES: Objection, Your Honor, I believe the witness has just testified to what his impression

was. I think that based on Your Honor's order, it goes beyond the scope of what he can testify to. He can testify to what was said to him and what he said, but to the degree he starts talking about his impressions, and if those impressions are based upon any discussions with the client, they're based upon an area for which we have not been allowed to conduct discovery.

JUDGE CHAPPELL: I am going to sustain it. We don't need to hear what his impression is. He's a fact witness, isn't he?

MR. CURRAN: Yes, Your Honor.

JUDGE CHAPPELL: Sustained.

BY MR. CURRAN:

Q. But sir, there was no discussion of the patent litigation during either the Kenilworth meeting or the subsequent meeting or telephone conference that you just described?

A. That's correct.

Q. Sir, at either of those meetings, was there any reference to an entry date upon which Upsher-Smith could enter the market in resolving the patent litigation?

A. No.

Q. Was there any reference at either of those two meetings to 180-day exclusivity?

A. No.
Q. Are you familiar with that term?
A. I am.
Q. Sir, at either of those two meetings or conferences, was there any statement by anyone that Upsher-Smith should be paid for delayed entry?
A. No.
Q. Sir, what happened next after this telephone conference? I call it a telephone conference, from your perspective anyway.
A. It was -- yes, from my perspective, it was a telephone conference.
Q. Okay. What happened after this telephone conference?
A. Within a day or two after the conference, I received a telephone call from Mr. Troup. I remember it specifically because it was about midmorning, and I'm on my firm's management committee, and we were in a management committee meeting, but I was -- my secretary brought in a note, told me it was Mr. Troup and that he would like me to step out if I could. And I did, and I took the call.
Q. Okay. What did you do after speaking to Mr. Troup?
A. I endeavored to memorialize the terms of the

agreements that Upsher-Smith and Schering-Plough had reached.

Q. Did you do that?

A. I did. I drafted something that I labeled Points of Agreement.

Q. Mr. Cannella, I'd like to ask you to look in that binder again, and I'd like to ask you to look at the document under tab 20. Now, disregarding for the moment the first page, the fax transmittal, what are the other pages under that tab?

A. They are -- the first three pages beyond the fax transmittal page are the Points of Agreement, and the next page -- I'm sorry, the next two pages are Attachment A referred to in the Points of Agreement. This is what I drafted.

MR. CURRAN: Your Honor, at this time I move for the admission of USX 233 into evidence.

MR. KADES: I have no objection, Your Honor.

MR. NIELDS: No objection, Your Honor.

JUDGE CHAPPELL: USX 233 is admitted.

MR. CURRAN: Thank you, Your Honor.

(USX Exhibit Number 233 was admitted into evidence.)

BY MR. CURRAN:

Q. Mr. Cannella, just for the record, there are

certain redactions noted on the second page of this exhibit.

A. I see that.

Q. All right. Those redactions were not there when you prepared the document, correct?

A. That is correct.

Q. And just for the record, this copy of the document came out of Schering-Plough's production, but they must have had some attorney comment on here, but it appears in doing the redaction certain language was omitted in paragraph 3.

A. Yes, I see that.

Q. Do you see that, sir?

A. I do.

Q. Do you recall what that said?

A. Well, I can't give you it back verbatim, but I believe it said, "in the event in the future any governmental agency or court of last resort."

Q. Sir, what happened next after you prepared the Points of Agreement?

A. I sent my draft out to Upsher-Smith to make sure that it accurately reflected the various agreements that the parties had come to. That was confirmed to me, and then the document was transmitted to Schering-Plough.

Q. What happened next after this Points of Agreement and the attachment were provided to Schering-Plough?

A. Well, my best recollection is that having learned that the document was in Schering-Plough's hands but having not heard anything from Schering-Plough, that I called John Hoffman and asked as to the status.

Q. What did he say?

A. He told me that they had the Points of Agreement, that they were working on a more detailed document. I inquired when we were likely to see it. He told me he wasn't entirely sure. And then we waited for it.

Q. Did you -- you didn't wait forever. What happened next?

A. Well, I was a little concerned with the passage of time since I wanted to at least be able to call home and tell my wife when I might be coming home, but eventually we did receive a new document from Schering-Plough which was Schering-Plough's version of what the agreement should look like.

Q. Sir, I'd like to direct your attention to the document under tab 21. Do you see a multipage document there labeled USX 105?

A. I do.

Q. Sir, is that the revised draft, if you will, that you just referred to?

A. I wouldn't call it a revised draft, because they did not -- Schering didn't work off the Points of Agreement and revise the Points of Agreement. They provided a new document, but that is the new document that I referred to earlier.

Q. What happened -- what did you do after receiving this new document?

A. Well, I see from the fax cover sheet that it was apparently sent both to me and to Ian Troup simultaneously. I unquestionably had conversations with Mr. Troup about the new document. And I then subsequently had a series, although I cannot quantify the number, but a series of telephone conversations with Mr. Hoffman concerning the Schering-Plough version of the document and why it was not acceptable to Upsher-Smith.

Q. Sir, ultimately, did you -- well, ultimately, did Upsher-Smith and Schering reach agreement on the terms?

A. They did, but Mr. Hoffman and I were unable to reach that agreement, so at some point in these discussions, the suggestion was made -- and I believe I

made it -- that it made sense to get the principals back onto the telephone to seek their guidance as to how to resolve some of the differences the lawyers were having with the form of the agreement.

Q. Sir, do you remember what issues the lawyers couldn't resolve?

A. In general terms, yes.

Q. What were they?

A. The Points of Agreement which I had sent over acknowledged that Schering-Plough owned the patent that was at issue in the lawsuit but did not acknowledge any liability or wrongdoing on behalf of Upsher-Smith. The Schering-Plough version reflected in tab 21 had provisions -- and I'm doing this without looking at the document -- but had provisions that dealt with admissions by Upsher-Smith that the Schering-Plough patent was valid and enforceable and admissions that the planned Upsher-Smith product infringed that patent, and those were not acceptable.

There were additional provisions that were not acceptable having to do with the scope of the license grant with respect to the Schering-Plough to Upsher-Smith license.

Q. Sir, I'd like to direct your attention to the document under tab 22.

A. Yes.

Q. Okay, this document is already in evidence, but I'd like to ask you to identify it, if you can.

A. This is the agreement that the parties initialed and signed on the night of June 17th or perhaps after midnight, so it might have actually been June 18th.

Q. Sir, I'd like to direct your attention to the fifth page under that tab, which bears the number at the bottom (i).

A. Yes.

Q. And specifically, I'd like to direct your attention to paragraphs 1 and 2 there.

A. Yes.

Q. Do those paragraphs represent the ultimate outcome of this dispute you referred to a moment ago?

A. Yes.

Q. I'd like to ask you to compare those paragraphs in USX 104, which is under tab 22, to the counterpart sections in USX 105, which is the document under tab 21.

A. Well, as you can see, in the draft that Schering-Plough sent, paragraph 1 says that Upsher-Smith agrees that U.S. patent number 4,863,743, owned by Key Pharmaceuticals, Inc. (the '743 patent) is

valid and enforceable. As I said earlier, we were not willing or Upsher-Smith was not willing to make that agreement, so the principals were brought, as I said, back onto the telephone. This was discussed with them. They resolved the difference. Mr. Kapur said that Upsher-Smith's version was indeed what he had in mind. And the final agreement reads in the place of that paragraph 1, this paragraph 1:

"Upsher-Smith agrees that Key Pharmaceuticals, Inc. is the owner by assignment of the entire right title and interest in United States Patent Number 4,863,743 (the '743 patent)."

Q. So, instead of acknowledging --

A. Validity and enforceability.

Q. -- yeah, instead of acknowledging validity and enforceability and infringement, correct?

A. No, paragraph 1 only dealt with validity and enforceability.

Q. Okay, take a look at paragraph 2.

A. Paragraph 2 in the draft that Schering-Plough provided, the interim draft is what I'll call it to keep the record clear, had Upsher-Smith, "acknowledges and agrees that its Klor Con M20 potassium chloride product is covered by and infringes the '743 patent." That was another one of the provisions that was not

acceptable on the Upsher-Smith side. It was another one of the provisions that we had the discussion with the principals about after Mr. Hoffman and I had been unable to reach agreement just among the lawyers.

And again, the principals acknowledged what they intended, and that became paragraph 2 of the agreement that they signed, which paragraph 2 parallels what I had said in the Points of Agreement earlier in the day, and I can read it into the record if you desire or I cannot.

Q. No, I don't think that's necessary, thank you, sir.

All right, we've just dealt with paragraphs 1 and 2. I'm looking at, again, the final agreement, USX 104 under tab 22. I'd like to direct your attention to paragraph 3 immediately below what we just discussed.

A. Yes.

Q. I want to read that, and then I'm going to ask you a question about it. It states:

"Upsher-Smith agrees that it will not market in the United States its Klor Con M20 potassium chloride product or any other sustained release microencapsulated potassium chloride tablet prior to September 1, 2001."

Do you see that sentence?

A. I do.

Q. Was that sentence the subject of discussion and negotiation by you that evening or early morning?

A. Yes, it was.

Q. Okay. What was discussed or negotiated with respect to that?

A. Well, again, perhaps the easiest way to do it is for me to refer back to the interim draft that we received from Schering-Plough. Schering-Plough's version of that sentence read, "Upsher-Smith agrees that it will not market in the United States its Klor Con M20 potassium chloride product or any other 20 milliequivalent potassium chloride product prior to September 1, 2001."

That language was, from Upsher-Smith's perspective, too broad. It covered too much and prohibited --

MR. KADES: Objection, Your Honor.

THE WITNESS: -- too much.

MR. KADES: Lack of foundation for what the witness just testified to.

MR. CURRAN: I can rephrase the question, and I'm sure that will satisfy that objection, Your Honor.

JUDGE CHAPPELL: Okay, so you're going to withdraw the question, he's going to withdraw the

objection.

MR. KADES: Yes, Your Honor.

MR. CURRAN: What was said in the answer?

BY MR. CURRAN:

Q. Mr. Cannella, what did you or Mr. Troup say to Schering-Plough about their proposed language in that first sentence in paragraph 3?

A. In my conversations with Mr. Hoffman, I told him that the language was too broad. It covered too -- it prohibited Upsher-Smith from doing too broad a spectrum of activities and was not acceptable.

In the subsequent conversation where we had the principals on the phone, I explained Upsher-Smith's position to Mr. Kapur. Mr. Kapur understood it and agreed that the language was too broad, and we narrowed the language to the language that now appears in the final version, USX 104, which now -- which then read, "or any other sustained release microencapsulated potassium chloride tablet."

Q. Okay. What you just read is the -- what was ultimately adopted in the agreement, correct?

A. That's correct.

Q. And the -- before that, that parenthetical expression was different, and it read, "or any other 20 mEq potassium chloride product"?

A. That's correct.

Q. So, it was just that parenthetical expression that was the subject of discussion as far as that particular sentence goes, correct?

A. That's correct.

Q. Okay. Sir, where did the September 1, 2001 date come from?

A. It was given to me earlier that day, and I incorporated it into the Points of Agreement.

Q. Was that the subject of negotiation that evening or that early morning?

A. No.

Q. And again, had that been the subject of negotiation at the meeting in Kenilworth?

A. No.

Q. Had that been the subject of negotiation at the telephone conference after the meeting in Kenilworth?

A. No.

Q. Sir, I want to direct your attention, still within the final version of the agreement, USX 104, to the paragraph numbered 11.

A. Is that paragraph number 11 in the cover letter or in the attached -- in Exhibit A?

Q. In Exhibit A, sir.

A. Yes.

Q. Okay. That's the page, that (iii) at the bottom?

A. Correct.

Q. FitzCella 0136.

A. Yes.

Q. Sir, let me ask a question generally, then I am going to refer you specifically to this language.

Was Schering-Plough paying money to Upsher-Smith to delay entry in this agreement?

A. No.

MR. KADES: Objection, Your Honor, no foundation for the witness' knowledge.

MR. CURRAN: Oh, quite the contrary, Your Honor. We've spent all evening laying the foundation. This man participated in the negotiations, he was at the front lines of the negotiations, he's in a position to comment on the parties' intentions as well as anyone.

MR. KADES: Your Honor, unless --

JUDGE CHAPPELL: Are you asking if he advised them to pay money?

MR. CURRAN: No.

JUDGE CHAPPELL: Why --

MR. CURRAN: I'm asking what the intent of the parties were in this agreement.

MR. KADES: Your Honor, unless Counsel for Upsher can establish that his knowledge is based only on nonprivileged information, then testimony that relies as a basis on privileged information is evidence that we do not -- did not have a chance to conduct discovery on, and therefore, we are unable to conduct a fair cross. When they decided to assert the privilege in discovery as to the matters that they discussed internally relating to the settlement, they made the choice that -- to assert the privilege. They now can't rely on inferences drawn based on those privileged discussions.

JUDGE CHAPPELL: I agree. The way the question's worded, the objection is sustained.

BY MR. CURRAN:

Q. Sir, I'd like to direct your attention to paragraph 11.

A. Yes.

Q. Do you see the language where it says, "In consideration for the licenses, rights and obligations described in paragraphs 1 through 10 above"?

A. I do.

Q. "SP Licensee shall make the following payments to Upsher-Smith"?

A. Yes.

Q. Was that language intended to indicate that money was being paid in connection with the patent settlement?

MR. KADES: Objection, Your Honor, same basis. He's asking him for what his understanding of the intention of the parties was.

MR. CURRAN: I'd like to address that, Your Honor.

JUDGE CHAPPELL: All right.

MR. CURRAN: Two points: One, here last night, almost exactly 24 hours ago, Mr. Orlans from complaint counsel asked these same types of questions to Schering-Plough's attorney Mr. Hoffman. If they can do it, we can do it.

JUDGE CHAPPELL: You're not going to be able to assert privilege and dance around it with a witness on the stand, Mr. Curran.

MR. CURRAN: I don't think I'm doing that.

JUDGE CHAPPELL: If you're not going to give them any information about any intent and any attorney communication, you are not going to get it in the side door. I don't care what Mr. Orlans did. Is that clear?

MR. CURRAN: Yes, Your Honor.

JUDGE CHAPPELL: You can't dance around -- you

can't assert the privilege and dance around the edges of it. Either it's there or it's not there. Do you want to waive the privilege?

MR. CURRAN: I don't want to waive the privilege, Your Honor.

JUDGE CHAPPELL: I'm giving you that choice right now if you want to waive the privilege and allow this information.

MR. CURRAN: I don't want to do anything to waive the privilege, Your Honor.

JUDGE CHAPPELL: All right, then that question is improper and the objection's sustained unless you lay some foundation that gets it away from any privileged communication, because when you're asking him what the intent of it was, it's entangled in what he talked to his client about.

MR. CURRAN: Well, then, Your Honor, then I move to strike the testimony of Mr. Hoffman yesterday under questioning by Mr. Orlans.

JUDGE CHAPPELL: Too late, that's overruled.

BY MR. CURRAN:

Q. Mr. Cannella, referring to paragraph 11?

A. Yes.

Q. Do you see in subparagraphs (i), (ii) and (iii), there's reference to up-front royalty payments?

A. Yes.

Q. Sir, do you see in subparagraph (iv), there's reference to milestone payments?

A. Yes.

Q. Sir, do you see in subparagraph (v), there's reference to royalties?

A. Yes.

Q. Sir, were there discussions between Upsher-Smith or Upsher-Smith representatives and Schering-Plough representatives as to those payments?

A. Yes.

Q. What were those discussions?

A. All of those discussions -- all of those discussions relating to those payments dealt with those payments as consideration from Schering-Plough to Upsher-Smith for Schering-Plough's acquiring of the rights in the four Upsher-Smith pipeline products.

Q. And that was said between the parties?

A. That's correct.

Q. Sir, was there discussion between the parties as to whether or not these payments were contingent or noncontingent upon anything?

A. Well, certainly -- the answer is yes.

Q. What was discussed or stated in that regard?

A. Well, with respect to the first payment --

well, indeed, with respect to the entire agreement, including the first payment, it was all contingent upon board approval by Schering-Plough. So, until there was Schering-Plough board approval, there was no entitlement to the payments.

Q. Beyond the board approval, was there any other discussion as to whether or not these up-front royalty payments were contingent or noncontingent?

A. Yes, I believe there was.

Q. What was stated in that regard?

A. Well, it was a staged payment. There were three "up-front payments," but the license grants from Upsher-Smith to Schering, which I believe are reflected in paragraphs 7, 8, 9 and 10 of the agreement, give Schering rights to certain things, including trade secrets and know-how.

The understanding between -- the discussion and understanding between the parties was that if Upsher-Smith somehow failed to provide that know-how and those trade secrets if called upon by Schering-Plough to provide it, that that would be -- would impact the rest of the agreement.

Q. Sir, I would like to direct your attention to paragraph 12, which is on page (v) for 5, FitzCella number 0138. Do you see that, sir?

A. I do.

Q. And this is also part of that Exhibit A to the final agreement, correct?

A. Yes, yes.

Q. Sir, I'm going to read that paragraph and then ask you if there was discussion about this provision.

"In the event that any court or governmental authority or agency rules that the licenses granted to the SP Licensee are void or invalid, then all such rights which are ruled to be invalid shall terminate and Upsher-Smith shall have the right, at its sole discretion, to purchase back, for nominal consideration, all such terminated rights. Any of Schering's payment obligations under the Detailed Agreement relating to such invalidated rights which have not become due and payable prior to the date of such ruling shall thereupon terminate."

Sir, was that provision the subject of discussion?

A. Yes.

Q. What was said about that provision?

A. I can't be precise as to who said what about the provision, but the parties clearly did discuss the concept of what happens if we need to unwind this deal, and this provision I believe is designed to cover that.

Q. Sir, I'd like to call your attention to paragraph 20, which is three pages later in the document.

A. Yes.

Q. Do you see that paragraph, sir?

A. Yes.

Q. I don't want to read this whole thing, but sir, that appears to be a force majeure provision, correct?

A. Correct.

Q. Sir, I want to call your attention specifically to the parenthetical, "except the obligation to make payments when properly due."

Do you see that?

A. I do.

Q. Let me ask two questions. First, was paragraph 20 the subject of discussion or negotiation at all between the parties?

A. No.

Q. Was the parenthetical within paragraph 20 that I've just read the subject of any discussion or negotiation between the parties?

A. No.

Q. Sir, I'd like to -- within the same document, I'd like to refer your attention to the third page from the start of the document. It's the page with the

number 2 at the bottom. That's because there is a cover letter on top.

A. Yes, I have it.

Q. Okay. And for the record, I want to know if this is FitzCella 0132.

A. That's correct.

Q. Sir, at the bottom of that page and then carrying over to the following page, there's another force majeure provision, correct?

A. Yes.

Q. Was that provision the subject of any discussion or negotiation between the parties?

A. No.

Q. Was the parenthetical expression "except the obligation to make payments when properly due" the subject of discussion or negotiation between the parties?

A. No.

Q. Sir, do you know how -- do you know where that language came from? Let me -- let me clarify the question.

Do you know where these force majeure provisions came from?

A. They came from Schering-Plough, and they appear to be boilerplate force majeure provisions.

MR. CURRAN: Your Honor, no further questions.

JUDGE CHAPPELL: Thank you.

Is Schering going to question this witness?

MR. NIELDS: No, Your Honor, we have no cross exam.

JUDGE CHAPPELL: Okay.

Any cross?

MR. KADES: Yes, Your Honor.

CROSS EXAMINATION

BY MR. KADES:

Q. Good evening, Mr. Cannella. My name is Michael Kades, and I'll be questioning you on behalf of complaint counsel.

Mr. Cannella, isn't it correct that you only attended one meeting in person with Schering representatives?

A. That's correct.

Q. And that's the meeting that occurred at -- a meeting that occurred in around June 10th, 11th or 12th at Schering's offices?

A. That's correct.

Q. You weren't at a meeting with Mr. Troup and Mr. Driscoll in Mr. Driscoll's office in the spring of 1997?

A. I was not.

Q. So, you have no firsthand knowledge of what was discussed at that meeting?

A. I do not.

Q. You were not at a May 28th meeting at Upsher-Smith's offices to discuss the patent litigation between Upsher and Schering?

A. I was not.

Q. So, you have no firsthand knowledge of what was discussed at that meeting.

A. I do not.

Q. You were not at a June 3rd, 1997 meeting held at Upsher-Smith's offices.

A. I was not.

Q. So, you have no firsthand knowledge of what was discussed at that meeting.

A. That's correct.

Q. Now, Mr. Cannella, prior to your -- the Kenilworth meeting, you said you had a phone call with Mr. John Hoffman?

A. That's correct.

Q. And I believe you testified that in that conversation, Mr. Hoffman raised antitrust sensitivities about the upcoming meeting?

A. Yes, he did.

MR. KADES: Your Honor, may I approach the

witness?

JUDGE CHAPPELL: Yes.

BY MR. KADES:

Q. Mr. Cannella, I'm handing you what is the transcript from the deposition you gave in October of this year.

A. Yes.

MR. CURRAN: I'd like a page reference, if I may.

MR. KADES: I will get you a page reference.

BY MR. KADES:

Q. If you would turn to page 50 of your -- of the transcript.

A. I'm sorry, page 50?

Q. Yes, 5-0.

A. Yes.

Q. Now, at page 50, you were asked:

"QUESTION: I believe you mentioned that prior to this meeting, you had a telephone conversation with Mr. Hoffman concerning setting up this meeting. Is that correct?

"ANSWER: That's my general recollection, yes.

"QUESTION: Was anybody other than yourself and Mr. Hoffman present during that -- during that telephone conversation?

"ANSWER: I don't believe so.

"QUESTION: You mentioned that that telephone conversation related to setting up the logistics of the meeting and I believe excluding the debate over the merits of the lawsuit. Is that correct?

"ANSWER: Yes.

"QUESTION: Was there anything else mentioned or discussed in that telephone conversation with Mr. Hoffman?

"ANSWER: Not that I recall."

Was that your testimony, sir?

A. Yes, it was, but as that testimony indicates, I had been asked about that subject matter earlier in the deposition, and earlier in the deposition, I -- I don't know exactly where you'll -- you'd find it, sir, but earlier in the deposition, I testified that Mr. Hoffman and I had a discussion of ground rules and I mentioned the ground rule of no debate. The other ground rule was the sensitivity to antitrust issues, which I did not mention, but I was not directly asked it.

Q. So, in the testimony -- the other testimony you're referring to, you mentioned the exclusion of the discussion about patent issues and ground rules. Is that correct?

A. I'm not sure I understand your question.

Q. Okay, well, why don't we take a look at that testimony. If you could turn to page 46?

A. Yes.

Q. I believe beginning on page 8 -- there's testimony from you, "I cannot be terribly precise, Mr. Narrow, but I do recall that prior to the meeting, I was involved in a telephone discussion with Mr. Hoffman, the in-house lawyer from Schering-Plough, and my recollection of that conversation was that it was designated primarily to set up the logistics of the meeting, to identify the participants and to lay the ground rules that this was not to be a debate over the merits of the lawsuit but an opportunity for the business people to explore business opportunities together."

Was that the testimony you were referring to a moment ago?

A. Yes, it is.

Q. Mr. Cannella, you testified that the -- by the time of the settlement of the patent litigation, the summary judgment motions that Upsher had filed had not been granted.

A. That's correct.

Q. Had they been denied?

A. They had not.

Q. So, they were pending at the time of the settlement?

A. That's correct. Argument on those motions was heard the day before the trial was to start.

Q. Mr. Cannella, at the meeting you attended in New Jersey, did you say anything at all at that meeting?

A. I believe I answered that on direct. No, I did not.

Q. Now, and prior to the phone call with Mr. Hoffman, you had not had any dealings with anyone from Schering concerning settlement of the patent litigation.

A. That's correct.

Q. And besides the meeting you attended in New Jersey, the only communications with Schering that you participated in concerning the settlement of the patent litigation were those discussions that occurred on the day of the settlement.

A. No, that's not correct.

Q. If you would turn to page 71.

A. Yes.

Q. Starting at line 4:

"QUESTION: Subsequent to the meeting in New Jersey that you attended, did you participate in any

communications between Upsher-Smith and Schering-Plough concerning settlement of the '743 patent litigation?"

There was an objection.

"ANSWER: Yeah, if I'm understanding your question correctly, I would answer yes, because on the -- I guess on the day of the settlement, I participated in the discussions and the drafting of the papers memorializing the settlement and the business deal.

"QUESTION: Okay. Did you participate in communications between the parties concerning the settlement negotiations other than what you have just described which occurred on the day of the settlement?

"ANSWER: No."

Was that your testimony, sir?

A. It was. That's not inconsistent with what I said. I participated in a business arrangement exploration meeting in Kenilworth, New Jersey. I participated in a subsequent telephone conference where that business arrangement was the subject of the discussion. In neither of those discussions were settlement of the patent lawsuit discussed. The only time I became involved in any discussion that involved settlement of the patent litigation was on the day and night the papers were signed.

Q. Which I believe was my question to you before we went to your transcript.

A. If it was, I misunderstood it, sir.

Q. Mr. Cannella, on direct you testified that you also participated by phone in another conference after the New Jersey meeting.

A. Yes, that's what I just made clear to you, yes.

Q. And you testified that in that meeting, you have a general recollection that Mr. Kapur from Schering asked pointed questions about the Niacor-SR product?

A. I can't be precise as to which of the products he asked pointed questions about, but he certainly was informed as to the products that were being discussed.

Q. Do you remember any of the specifics that Mr. Kapur discussed?

A. I do not.

Q. Do you remember whether he discussed Schering's understanding of the FDA approval status of the products at issue?

A. I'm afraid I can't go to that level of detail as to a telephone conference five years ago.

Q. Do you remember whether Mr. Kapur discussed anything about the patent status of any of the products that Schering was considering licensing from Upsher?

A. I don't recall that discussion. I'm not saying it didn't take place, but I just don't recall.

Q. Do you recall whether Mr. Kapur discussed anything about the market potential of any of the products in that phone call?

A. Again, in general terms, yes, very clearly, the parties were discussing the market potential of the products. If you were to ask me to be specific on product by product what that discussion was and what the parties' respective views of their market potential was, I'm afraid I couldn't do that.

Q. Well, other than market potential, do you -- you don't remember the topics that Mr. Kapur discussed specifically at that phone conversation.

A. I wouldn't agree with that. I do recall, as I said earlier, that the parties discussed valuation of these products and what Upsher-Smith was looking for to transfer rights in the products and what Schering-Plough was offering to acquire those rights.

Q. In terms of the due diligence Schering had done as to the products, what topics did Mr. Kapur discuss?

A. I couldn't tell you with great precision.

Q. Can you tell us with any precision?

A. No.

Q. Mr. Cannella, you testified that there was no

discussion of an entry date related to the patent litigation at the New Jersey meeting that you attended.

A. That's correct.

Q. So, if Mr. Hoffman testified that there was, in fact, such a -- was such a discussion, his testimony would not comport with your memory of that meeting.

A. That's correct, it would not.

Q. And if Mr. Troup testified that there was discussions about the entry date at the meeting in Kenilworth, his testimony would not comport with your understanding.

MR. CURRAN: Objection, foundation, Your Honor.

MR. KADES: Your Honor, if I may be heard?

JUDGE CHAPPELL: Okay.

MR. KADES: Your Honor, I believe it is fair and the cross examiner is allowed to put questions to the witness where they have a good faith belief of the underlying facts, rather than taking everybody's time and going through the deposition testimony that Mr. Cannella -- or the investigational hearing of Mr. Troup that Mr. Cannella was not present for and which is not relevant to the question. As long as I have a good faith belief that, in fact, there is testimony in evidence, I can ask him the question.

MR. CURRAN: Your Honor, the question is also

argumentative. I think it lacks foundation. I agree, we don't want to spend too much time tracking down Mr. Kades' good faith belief here.

JUDGE CHAPPELL: Well, the way I read it on CaseView, if mine doesn't have a typo on it, it perhaps is somewhat argumentative, but it is cross examination. So, I'll overrule the argumentative objection, and he's just asking the witness to agree or disagree. I'm going to allow it. So, the objection's overruled.

BY MR. KADES:

Q. Do you need the question read back?

A. No, I really could use the question back. Thank you.

(The record was read as follows:)

"QUESTION: And if Mr. Troup testified that there was discussions about the entry date at the meeting in Kenilworth, his testimony would not comport with your understanding."

THE WITNESS: That's correct. I have no idea what Mr. Troup testified about, nor what Mr. Hoffman testified about.

MR. KADES: If I can have a moment, Your Honor?

JUDGE CHAPPELL: Yes.

MR. KADES: Well, Your Honor, showing that learned behavior, we start puffing time, I believe I

have taken less than a half hour, and I have no further questions.

JUDGE CHAPPELL: Not bad, but the official clock is the one on the CaseView, just so you know. You have nothing further.

Any redirect?

MR. CURRAN: No redirect, Your Honor.

JUDGE CHAPPELL: Okay. Is this witness subpoenaed to testify later in the case or is he finished?

MR. CURRAN: I believe he's finished, Your Honor. He appeared here today under subpoena.

JUDGE CHAPPELL: Okay.

Thank you, Mr. Cannella, you're excused.

THE WITNESS: Thank you, Your Honor.

JUDGE CHAPPELL: Remember tomorrow we're going to wrap up no later than 2:45, so between 2:30 and 2:45. We'll adjourn until tomorrow morning at 9:30.

(Whereupon, at 6:10 p.m., the hearing was adjourned.)

C E R T I F I C A T I O N O F R E P O R T E R

DOCKET/FILE NUMBER: 9297

CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

DATE: FEBRUARY 14, 2002

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: 2/15/02

SUSANNE BERGLING, RMR

C E R T I F I C A T I O N O F P R O O F R E A D E R

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

DIANE QUADE